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No. ———

IN THE
Supreme Court of the United States
OCTOBER TERM, 1990

AMERICAN IRON AND STEEL INSTITUTE,
Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

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October 1, 1990

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QUESTION PRESENTED

1. Whether the Environmental Protection Agency, in revising the national ambient air quality standard for particulate matter, violated Section 109(b)(1) of the Clean Air Act when it failed to determine the particulate matter level that it deems to be safe to "protect the public health" and separately to determine the additional protection necessary to provide an "adequate margin of safety," in each case articulating the scientific basis for its determination.

LIST OF PARTIES TO THE PROCEEDING BELOW

The case below was raised in six petitions for review of federal agency action filed in and consolidated by the United States Court of Appeals for the District of Columbia Circuit and docketed at Nos. 87-1438, 87-1441, 87-1442, 87-1443, 88-1913, and 89-1013. This Petition for a Writ of Certiorari is based on claims presented in petitions Nos. 87-1442, 87-1443, and 88-1913.

In Nos. 87-1442 and 87-1443, the American Iron and Steel Institute ("AISI")[1] was the petitioner, Alabama Power Company, *et al.*,[2] and the American Mining Con-

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[1] AISI is a trade association. AISI is not a corporation and does not have a parent or subsidiary company to be listed pursuant to Rule 29.1 of the Rules of the Supreme Court. Upon request, counsel can compile and supply to the Court a list of AISI's member companies.

[2] "Alabama Power Company, *et al.*," refers to Alabama Power Company, Appalachian Power Company, Baltimore Gas and Electric Company, Boston Edison Company, Carolina Power & Light Company, Centerior Energy Corporation, Cleveland Electric Illuminating Company, Toledo Edison Company, Central and South West Services, Inc., Central Power and Light Company, Public Service Company of Oklahoma, Southwestern Electric Power Company, West Texas Utilities Company, Central Hudson Gas & Electric Corporation, Central Illinois Light Company, Central Illinois Public Service Company, The Cincinnati Gas & Electric Company, Columbus Southern Power Company, Commonwealth Edison Company, Consolidated Edison Company of New York, Inc., Consumers Power Company, The Dayton Power and Light Company, Delmarva Power & Light Company, The Detroit Edison Company, Duke Power Company, Florida Power Corporation, Florida Power & Light Company, Georgia Power Company, Gulf Power Company, Houston Lighting & Power Company, Illinois Power Company, Indiana Michigan Power Company, Indianapolis Power & Light Company, Iowa-Illinois Gas and Electric Company, Iowa Public Service Company, Kansas City Power & Light Company, Kentucky Power Company, Kentucky Utilities Company, Madison Gas and Electric Company, Mississippi Power Company, Monongahela Power Company, Montaup Electric Company, New England Power Company, New York State Electric & Electric Gas Corporation, Northern Indiana Public Serv-

gress ("AMC") were intervenor-petitioners, the United States Environmental Protection Agency ("EPA") and the Administrator of the United States Environmental Protection Agency ("Administrator") were respondents, and the Natural Resources Defense Council, Inc. ("NRDC") was intervenor-respondent.

In No. 88-1913, AISI was petitioner, Alabama Power Company, *et al.*, were intervenor-petitioners, EPA was respondent, and NRDC was intervenor-respondent.

In No. 87-1438, NRDC, the State of Connecticut, the Commonwealth of Massachusetts, the State of New Jersey, the State of New York, and the State of Vermont were petitioners, the Administrator and EPA were respondents, and Alabama Power Company, *et al.*, AISI, AMC, and the National Coal Association ("NCA") were intervenor-respondents.

In No. 87-1441, AMC was petitioner, Alabama Power Company, *et al.*, and AISI were intervenor-petitioners, the Administrator and EPA were respondents, and NRDC was intervenor-respondent.

In No. 89-1013, AMC was petitioner, Alabama Power Company, *et al.*, and NCA were intervenor-petitioners, EPA was respondent, and NRDC was intervenor-respondent.

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ice Company, Ohio Edison Company, Pennsylvania Power Company, Ohio Power Company, Ohio Valley Electric Corporation, Oklahoma Gas and Electric Company, Pacific Gas and Electric Company, Pennsylvania Electric Company, Pennsylvania Power & Light Company, The Potomac Edison Company, Potomac Electric Power Company, Public Service Company of Indiana, Inc., Public Service Electric and Gas Company, Salt River Project, Southern California Edison Company, Tampa Electric Company, Tucson Electric Power Company, Union Electric Company, Virginia Power Company, West Penn Power Company, Wisconsin Electric Power Company, Wisconsin Power and Light Company, Wisconsin Public Service Corporation, the Edison Electric Institute, the National Rural Electric Cooperative Association, and the American Public Power Association.

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

The American Iron and Steel Institute ("AISI") respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit entered on April 27, 1990, in the case of *Natural Resources Defense Council, Inc., et al.* v. *Administrator, U.S. Environmental Protection Agency, et al.*, No. 87-1438 and consolidated cases.

OPINION BELOW

The April 27, 1990 opinion of the United States Court of Appeals for the District of Columbia Circuit in *Natural Resources Defense Council, Inc., et al.* v. *Administrator, U.S. Environmental Protection Agency, et al.*, No. 87-1438 and consolidated cases, is reported at 902 F.2d 962 and is reprinted in the Appendix to the Petition for a Writ of Certiorari (No. 90-257) filed by the National Coal Association ("NCA App.") at 1a.[1]

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[1] The Petition in No. 90-257, *National Coal Association v. Natural Resources Defense Council, Inc., et al.*, is from the same judgment

The opinion below addresses final rulemaking published by the United States Environmental Protection Agency ("EPA") entitled Revisions to the National Ambient Air Quality Standards for Particulate Matter, published at 52 Fed. Reg. 24634 (July 1, 1987), pertinent portions of which are reprinted in the Appendix ("App.") to this Petition at 1a-53a.

JURISDICTION

The judgment of the United States Court of Appeals for the District of Columbia Circuit was entered on April 27, 1990. *See* NCA App. at 1a. A timely filed petition for rehearing was denied by that court on July 3, 1990. NCA App. at 93a. This Petition is filed within 90 days of the July 3, 1990 denial of the petition for rehearing in accordance with 28 U.S.C. 2101(c) (1988) and Rules 13.1 and 13.4 of the Rules of this Court. This Court's jurisdiction is invoked pursuant to 28 U.S.C. § 1254(1) (1988).

STATUTE AND REGULATIONS INVOLVED

This case involves Section 109 of the Clean Air Act, as amended, 42 U.S.C. § 7409 (1982). The pertinent provisions of Section 109 and related Sections 108 and 112, 42 U.S.C. §§ 7408 and 7412 (1982), together with the regulations at issue herein are set forth in Appendix A and B hereto, respectively, at 54a and 1a.

STATEMENT OF THE CASE

This case addresses the manner in which EPA properly can exercise its far-reaching authority to set national ambient air quality standards under Section 109

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of the court below which is the subject of this Petition. This Petition presents different questions from those raised in No. 90-257. We believe the Court should grant review in No. 90-257 but do not plan to file a pleading in response to the National Coal Association Petition.

of the Clean Air Act.[2] Once EPA establishes a Section 109 standard, that standard, within statutorily-prescribed time periods, must be met in every corner of the country. Cities and industrial areas that fail to meet Section 109 standards are subject to severe regulatory and economic sanctions.[3] Individual plants and sources deemed to be contributing to air pollutant levels that exceed a Section 109 standard must install emission controls which require major expenditures for nonproduction-related equipment. Sources that violate their control requirements are subject to enforcement proceedings and civil penalties or criminal fines of $25,000 per day.[4]

As one commenter noted in 1974:

> The Clean Air Act, coupled with the new 1972 Water Pollution Control Act Amendments, grants regulatory power to the administrator of EPA far beyond that possessed by other traditional federal regulatory commissions. These two environmental acts regulate not just one or another industry type or practice, but rather regulate nearly all industry, and, more importantly, the behavior of all citizens, through transportation and other controls.

Jorling, *The Federal Law of Air Pollution Control*, FEDERAL ENVIRONMENTAL LAW, 1066 (1974). An unnecessarily stringent Section 109 standard can waste resources

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[2] 42 U.S.C. § 7409 (1982). Hereinafter, citations to the Clean Air Act are to sections of the Act. The Table of Authorities provides parallel citations to the United States Code.

[3] *See*, generally, Part D of Title I of the Clean Air Act and, in particular, Sections 172 (requiring the states to adopt stringent new planning and regulatory mechanisms for areas not meeting an NAAQS) and 176 (cutting off certain federal grants for areas not meeting an NAAQS and failing to take remdial measures required by Part D). *See also*, Section 110(a)(2)(I) (banning the construction or modification of major emission sources in areas not meeting an NAAQS and lacking an approved Part D plan).

[4] *See* Section 113(b), (c).

and impair American industry and its ability to compete internationally.

Section 109 requires EPA to establish national ambient air quality standards to "protect the public health" and further to specify an 'adequate margin of safety." The D.C. Circuit ruled in the case below and on two other occasions that EPA may set Section 109 standards without identifying either the level at which a particular pollutant is safe for the public health or the magnitude of the safety margin it applied to its safe exposure determination. The D.C. Circuit further stated in the decision below that "uncertainty" in the data relied upon by EPA made unnecessary any such "further articulation" of EPA's basis for its Section 109 standards.

A. EPA's National Ambient Air Quality Standards for Particulate Matter

The Clean Air Act, as enacted in 1970, established, among other things, a framework for the regulation of common, ubiquitous air pollutants. EPA first was required to identify air pollutants emitted from "numerous or diverse mobile or stationary sources" which in the ambient air "may reasonably be anticipated to endanger public health or welfare." Section 108(a)(1). For each pollutant so identified, EPA must issue national ambient air quality standards ("standards" or "NAAQS"). Section 109(a). So-called "primary" or health-related NAAQS must be set at levels which "allowing an adequate margin of safety, are requisite to protect the public health." Section 109(b)(1).

"Particulate matter" is a generic term for airborne particles (liquid droplets or solids) of chemically and physically diverse substances. Such particles originate from many natural and man-made sources, both mobile and stationary, ranging from dust storms, sea spray, and volcanic activity to dirt roads and various industrial and agricultural activities.

The first particulate matter NAAQS were adopted by EPA in 1971 and were expressed in terms of Total Suspended Particulate ("TSP"). TSP is a measure of particulate matter captured by an air sampling device known as a high volume sampler, which collects particles up to sizes of 25 to 45 micrometers.

In setting a 24-hour TSP primary standard in 1971, EPA relied on effects levels reported by British scientists in studies carried out in Greater London over two decades starting in the 1950s. EPA erred, however, by treating the British Smoke measurement units reported in the British studies as equivalent to the more particle-inclusive TSP measure used for the U.S. standards. This error, although never publicly acknowledged by EPA, was noted by the National Academy of Sciences in 1974 [5] and by EPA's own appointed science advisors.[6] By treating the TSP measure as equivalent to the British Smoke measure, EPA incorrectly ascribed adverse health effects to TSP levels half as high as the levels reported in the British studies upon which EPA relied.[7] Because of this and other errors, EPA's science advisors concluded in 1976 that revision of the scientific documents upon which the original particulate matter standards were based was "not only desirable, but necessary." [8]

Eight years later, in 1984, EPA proposed revisions to the particulate matter standards.[9] In the preamble

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[5] *See* 2 Sen. Comm. on Public Works, 93d Cong., 2d Sess., Air Quality and Automobile Emission Control 401 (Comm. Print 1974).

[6] *See* National Air Quality Criteria Advisory Committee, Science Advisory Board, Report on Air Quality Criteria for Particulate Matter (1976).

[7] *Id.* at 27.

[8] *Id.* at 1.

[9] *See* Proposed Revisions to the National Ambient Air Quality Standards for Particulate Matter, 49 Fed. Reg. 10408 (Mar. 20, 1984).

thereto, then EPA Administrator Ruckelshaus stated that "the selection of a single air quality standard . . . presents an extraordinarily difficult regulatory problem, one for which the existing legislative decision criteria may well be inadequate." 49 Fed. Reg. at 10409. He further noted that the scientific data base for applying an adequate margin of safety was "even more sparse and uncertain," and that "[n]o 'scientific' approach for selecting any single recommended standard seems possible against this background." *Id.*

The Administrator noted that the courts "appear" to have ruled out consideration of economic and technological factors in setting ambient standards, leaving "some doubt whether the Administrator may even consider the practical problems of implementation to guide his choice." *Id.* EPA's public health review as of that date "revealed no scientific method of assessing exactly what level of standards public health requires. The scientific review indicates substantial uncertainties concerning the health risks associated with lower levels of particulate matter." *Id.*

Because of this "substantial degree of uncertainty," EPA proffered "ranges of interest" from which the final standards likely would be chosen. *Id.* at 10415. EPA proposed to select (1) a 24-hour primary standard from a range of 150 to 250 micrograms per cubic meter ($\mu g/m^3$), and (2) an annual primary standard from a range of 50 to 65 micrograms per cubic meter ($\mu g/m^3$). *Id.* at 10408. EPA also proposed to replace TSP as the indicator for particulate matter with a new, size-specific indicator designed to measure only particles with an aerodynamic diameter equal to or smaller than 10 micrometers. *Id.* EPA had determined that TSP particles larger than 10 micrometers had no significant impact on health and, therefore, should not be regulated. *Id.* at 10412. EPA referred to the new indicator as PM_{10}. *Id.*

In its June 3, 1985 comments [10] on the proposed PM_{10} standards, AISI objected to EPA's attempt to inject scientific uncertainty as justification for maintaining the erroneously stringent TSP standards as a basis for the new PM_{10} standards. By 1984, the scientific community, if not EPA, generally had acknowledged that the present standards were scientifically invalid because of the faulty application of British Smoke measurements.[11] AISI also quoted from remarks presented by Dr. A. Fraas of the Office of Management and Budget noting that since EPA was "unable to identify any clear evidence of adverse health effects at or near current ambient levels, it has made the uncertainty in the available evidence into a virtue by arguing that the current statute requires a conservative approach to protecting public health." [12]

AISI further stated in its comments that EPA cannot use the lack of scientific evidence absolutely ruling out adverse health effects at low levels of PM_{10} exposure to set the primary NAAQS essentially at any level it pleases. Such use by EPA of Section 109, if permitted, would indicate an excessive delegation to EPA of legislative power which would raise Constitutional questions.[13]

EPA promulgated the final standards on July 1, 1987.[14] EPA retained the PM_{10} indicator but selected the final standards from the bottom of its proposed ranges. The final 24-hour standard was set at 150 micrograms per cubic meter ($\mu g/m^3$), and the annual standard was set at 50 micrograms per cubic meter ($\mu g/m^3$). EPA's regulatory impact analysis predicted that attaining the new

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[10] AISI's June 3, 1985 comments ("AISI Comments") were docketed in the PM_{10} rulemaking proceeding at No. A-82-37, IV-D-254.

[11] *See* p. 5 *supra.*

[12] AISI Comments at 88.

[13] AISI Comments at 98-101.

[14] *See* Revisions to the National Ambient Air Quality Standards for Particulate Matter, 52 Fed. Reg. 24634 (July 1, 1987), App. 1a.

standards at these levels would cost nearly $2 billion (discounted present value in 1983),[15] one tenth of which, or approximately $200 million, will be borne by the steel industry.[16]

On October 28, 1987, AISI submitted a Petition to EPA for Reconsideration of the final standards on the basis of (a) new health effects data which AISI submitted with its Petition, and (b) the D.C. Circuit's decision in *Natural Resources Defense Council, Inc. v. Administrator, U.S. Environmental Protection Agency*, 824 F.2d 1146 (D.C. Cir. 1987) (*en banc*) (*Vinyl Chloride*) (holding that EPA, in establishing emission standards for hazardous air pollutants under Section 112 of the Act, must separately determine a "safe" level of exposure prior to applying an ample margin of safety). More than a year later, EPA denied AISI's Petition for Reconsideration.[17]

B. The Proceedings Below

Pursuant to and under the authority of Section 307(b)(1) of the Act, AISI appealed EPA's final standards and EPA's denial of AISI's Petition for Reconsideration in petitions for review filed in the D.C. Circuit and consolidated with others in the case below. AISI challenged the final standards on a number of scientific and legal grounds as arbitrary and capricious and contrary to law. AISI also pointed out that EPA failed to identify a safe level for PM_{10} contrary to the requirements of Section 109 of the Clean Air Act and contrary to the D.C. Circuit's *Vinyl Chloride* decision.

The panel below excused EPA's failure to denote a "safe" level of exposure for PM_{10} by reasoning that the

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[15] Regulatory Impact Analysis of the National Ambient Air Quality Standards for Particulate Matter, Second Addendum (Dec. 1986) at II-20.

[16] *Id.* at II-25.

[17] *See* 53 Fed. Reg. 52698 (Dec. 29, 1988).

Vinyl Chloride decision construing Section 112 of the Clean Air Act did not apply to determinations under Section 109.[18] The court below found that the uncertainty of the data upon which the Administrator based the final standards made it unnecessary for EPA to articulate the "risk it considered tolerable in meeting the requirements of providing a reasoned explanation for an administrative decision." [19]

Alabama Power Company, *et al.*,[20] intervenors in the D.C. Circuit proceedings below, filed a timely petition for rehearing and suggestion for rehearing *en banc* on an unrelated issue involving acid deposition. The court below denied the petition and suggestion on July 3, 1990.

REASONS FOR GRANTING THE WRIT

This Court has decided twelve cases arising under the Clean Air Act since that act was first enacted twenty years ago in 1970. To date, however, this Court has not heard a case involving Section 109, the most pervasive and far-reaching provision in the statute. Section 109 gives the Administrator the power to dictate the contents of the air we breathe and in so doing can redirect massive capital investment from growth and increased production to air emission control systems. To the extent Section 109 standards are unnecessarily stringent, plants may be shut down and jobs lost, with concomitant social and economic dislocation and a variety of adverse direct and indirect effects, including deterrence of new investment and impaired international competitiveness.

Although the impact of the PM_{10} standards is nationwide, only one court, the U.S. Court of Appeals for the District of Columbia Circuit, may review their propriety.

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[18] *Natural Resources Defense Council, Inc. v. Administrator, U.S. Environmental Protection Agency*, 902 F.2d 962, at 973-74, NCA App. at 22a-23a.

[19] *Id.* at 974, NCA App. at 23a.

[20] *See* p. ii n.2, *supra*, for a list of these companies.

See Section 307(b)(1). Any challenge to the PM_{10} standards must be brought within 60 days of promulgation. *Id.* Thereafter, the PM_{10} standards are not subject to challenge, not even as a defense in civil or criminal enforcement proceedings. Section 307(b)(2). The Clean Air Act's judicial review preclusion provisions thus eliminate any possibility of a conflict among the circuits or any further challenges to the PM_{10} standards. Unique issues raised by the PM_{10} standards will not develop, ripen, or otherwise become more focused in other forums over time. Now that the D.C. Circuit has acted, only the Supreme Court may address the issues raised by the PM_{10} standard and only on this singular occasion.

I. EPA MUST IDENTIFY A SAFE EXPOSURE LEVEL FOR THE POLLUTANTS IT REGULATES UNDER SECTION 109

Congress did not and cannot make in Section 109 an unfettered delegation to EPA of authority to set standards of critical and national importance. Section 109(b)(1) requires that NAAQS

> shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.

On its face, Section 109(b)(1) thus imposes three, separate limits upon EPA's standard setting discretion. First, Section 109(b)(1), requires that primary NAAQS "shall be based on . . . criteria" identified pursuant to Section 108. Second, primary NAAQS must be "requisite to protect the public health." Third, primary NAAQS must allow an "adequate margin of safety."

With regard to the first limit or requirement, that NAAQS be based upon criteria identified by EPA pursuant to Section 108, AISI raised numerous objections below to EPA's mischaracterization and misuse of the available scientific data in the particulate matter criteria

document and in setting the final primary PM_{10} standards. For example, as already noted,[21] EPA misapplied the British data upon which it relied in setting its original 1971 TSP standards, making the TSP standards at least twice if not three times too stringent, and never acknowledged or corrected that error but rather perpetuated it when EPA set the new PM_{10} standards.

For purposes of this Petition, however, AISI focuses on the second and third requirements of Section 109. EPA has failed to identify either the level of PM_{10} "requisite to protect the public health" or the magnitude of the "adequate margin of safety" which it applied to that level. EPA declined to make similar determinations when it established an NAAQS for lead in 1978. The D.C. Circuit upheld this omission in *Lead Industries Association v. EPA*, 647 F.2d 1130 (D.C. Cir.), *cert. denied*, 449 U.S. 1042 (1980) (*Lead*). EPA again failed to make these determinations in establishing a revised NAAQS for ozone in 1979. The D.C. Circuit excused this omission in *American Petroleum Institute v. Costle*, 665 F.2d 1176 (D.C. Cir. 1981), *cert. denied*, 455 U.S. 1034 (1982) (*Ozone*).

In 1976 and 1985, in separate proceedings respectively establishing and retaining with minor revisions an emission standard for the hazardous air pollutant vinyl chloride under Section 112 of the Clean Air Act, EPA again did not identify a health effects threshold for vinyl chloride, a strong carcinogen. Section 112 requires EPA to establish standards governing emissions of hazardous air pollutants at levels that "protect the public health" with an "ample margin of safety." Section 109 has similar requirements but requires a lesser, "adequate" margin of safety.

In the *Vinyl Chloride* case, *supra*, which reviewed EPA's withdrawal of proposed amendments to the Section 112 vinyl chloride standard, Petitioner Natural Resources

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[21] *See* p. 5 *supra*.

Defense Council, Inc. argued that the mandate to protect the public health with an "ample" margin of safety required that all emissions of vinyl chloride be banned. *See* 824 F.2d at 1152. This contention was unanimously rejected by the D.C. Circuit sitting *en banc*. *Id.* at 1154. Instead, the D.C. Circuit reversed and remanded the vinyl chloride standard because EPA had failed to make basic determinations required by the Act. The D.C. Circuit stated that, in setting national emission standards for hazardous air pollutants under Section 112, "the congressional mandate to provide 'an ample margin of safety' 'to protect the public health' requires EPA to make an initial determination of what is 'safe'." *Id.* at 1164. EPA may not consider cost or technical feasibility in determining what is "safe"; such a determination must be "based solely upon the risk to health." *Id.* at 1166. Noting that "safe" does not mean "risk-free," the D.C. Circuit ruled that EPA "must" decide "what risks are acceptable in the world in which we live." *Id.* at 1165. Once EPA has determined a "safe" level of exposure, the D.C. Circuit found that EPA could weigh considerations in addition to health such as cost or feasibility in applying the "ample margin of safety" required by Section 112. *Id.*

The *Vinyl Chloride* decision was handed down shortly after EPA issued the final PM_{10} standards. AISI submitted a Petition to EPA for Reconsideration of the final PM_{10} standards, in part to give EPA an opportunity to apply the *Vinyl Chloride* analysis and to evaluate the degree of "safety" that would be provided by the various levels within the ranges proposed for the primary PM_{10} standards. Both EPA, in denying AISI's Petition for Reconsideration, and the court below refused to apply the *Vinyl Chloride* rationale to EPA's standard setting under Section 109.

The court below found that "the two-step methodological requirement endorsed by *Vinyl Chloride* was neces-

sary because of the need under § 112 to sever determinations that must be based solely on health considerations from those that may include economic and technological considerations." 902 F.2d at 973, NCA App. at 22a. Noting its previous *Lead* and *Ozone* decisions (*id.*, NCA App. at 21a), the court below stated that EPA may not consider cost or technological feasibility at any stage of standard setting under Section 109. *Id.*, NCA App. at 22a. Because of this, the court below found that the rationale for separate identification of a safe level and the margin of safety applied thereto was "inapposite" to actions under Section 109. *Id.* This "foreclosure from consideration of cost and technological feasibility" persuaded the court below that Section 109 "itself does not mandate the methodological requirement we found necessary under § 112." *Id.*, NCA App. at 23a.

The concern of the court below over economic and technological feasibility is misplaced. The mandate in Sections 109 and 112 "to protect the public health" necessitates a "safe" exposure level determination whether or not EPA considers such other factors as economic or technological feasibility. *See, Vinyl Chloride*, 824 F.2d at 1164-65 & n.11.

The distinction between Section 112 for vinyl chloride and Section 109 for PM_{10} proffered by the court below makes no rational sense. Vinyl chloride is a "strong carcinogen" with a long and uncertain latency period.[22] The evidence in that case suggested that there was no apparent safe exposure level for vinyl chloride.[23] Despite the extreme dangers and substantial uncertainties posed by the chemical in question, the D.C. Circuit in *Vinyl Chloride* found that EPA's standard setting responsibilities included the identification and determination of certain parameters such as a safe exposure level and the

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[22] *Vinyl Chloride*, 824 F.2d at 1148.

[23] *Id.*

magnitude of the margin of safety applied to that level. With respect to PM_{10}, however, a relatively benign pollutant at lower concentration levels with only minimal transitory effects on even the most sensitive populations, the court below declined to impose the minimal procedural requirements the *Vinyl Chloride* decision found inherent in Section 112.

When dealing with more dangerous, life-threatening Section 112 hazardous chemicals or carcinogens for which an "ample" margin of safety is to be applied, EPA is required to determine the safe exposure level and not just a final standard with an unquantified, purportedly "ample" margin of safety. EPA should not be given more discretion and held to a lower standard of care and articulation when it addresses commonplace pollutants addressed by Section 109, to which a less than ample, "adequate" safey margin is to be applied.[24] The Clean Air Act requires EPA to make certain fundamental determinations in setting standards for dangerous pollutants. Certainly such procedures should be applied to the establishment of nationally applicable standards for the ubiquitous but considerably less dangerous pollutants regulated under Section 109, particularly since overly stringent standards can result in plant shutdowns, widespread unemployment and adverse health impacts found to result from unemployment.

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[24] Section 109 pollutants are widespread and commonly encountered (resulting from "numerous or diverse mobile or stationary sources") and "may reasonably be anticipated to endanger public health or welfare." Section 112 hazardous air pollutants, however, are less common but when encountered "may reasonably be anticipated to result an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness."

II. BY FAILING TO DEFINE SAFE EXPOSURE LEVELS FOR ITS SECTION 109 STANDARDS EPA HAS EXCEEDED ITS STATUTORY AUTHORITY AND PREVENTED MEANINGFUL JUDICIAL REVIEW

If, as concluded by the D.C. Circuit on three separate occasions in the *Lead* and *Ozone* decisions and the present PM_{10} decision, EPA has discretion to establish an ambient standard without ever having to determine what air quality level is "safe," or what is an adequate margin of safety, EPA can, as it proved with the PM_{10} standards, choose virtually any level, and its selection is essentially unreviewable. EPA need only state for the record that it reviewed the available scientific evidence, state that its review disclosed no obvious answers, and then select a number, any number for the final standard. The court below gives EPA this latitude because it won't require EPA to identify the "safe" exposure level as a benchmark against which to compare the standard.

Instead, the decision below announces the proposition that the greater the scientific uncertainty, the greater the latitude to be accorded the agency and the less articulation is required. 902 F.2d at 974, NCA App. at 23a. In other words, the less support EPA can adduce for a Section 109 standard, the greater the deference EPA is to be accorded. Such deference seriously reduces, if not eliminates, any meaningful role for the reviewing court. Absent any indication in the record of what risks EPA deems to be acceptable, the reviewing court has no basis against which to evaluate EPA's judgment.

The decision below actually excuses, and conceivably encourages, scientific imprecision and lack of data for governmental standard setting. If scientific uncertainty increases agency discretion, and, in turn, judicial deference, agencies have no impetus to generate or commission the scientific data necessary for setting standards.

Under a proper reading of Section 109, not only is EPA required to identify both the health protective limit

and the margin of safety applied thereto, EPA also is required to articulate clearly and separately the appropriate factors relevant to each such determination. Such a delineation is necessary to assure that each determination is made in a rational manner with due consideration of the different factors applicable to each and to assure that the courts are able to discharge their review function properly. As this Court aptly pointed out:

> Expert discretion is the lifeblood of the administrative process, but "unless we make the requirements for administrative action strict and demanding, expertise, the strength of modern government, can become a monster which rules with no practical limits on its discretion" (citation omitted).

Burlington Truck Lines v. United States, 371 U.S. 156, 167 (1962).

To permit EPA to speculate as to theoretical health risks, without regard to the certain harm to the public welfare that flows from unduly stringent standards and without guidance as to where on the continuum of relative safety the Administrator should draw his line, as the decision of the court below permits, would be a "sweeping delegation of legislative power" that raises serious Constitutional questions. *See, A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 539 (1935); *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935). *See also Industrial Union Dep't. AFL-CIO* v. *American Petroleum Inst.*, 448 U.S. 607 (1980) (Plurality Opinion), 671 (Rehnquist, J., concurring in the judgment). The Court need not address this issue here, however, because the court below erred in its construction of the basic requirements of Section 109.

This Court should clarify the requirements of Section 109 by granting this Petition and by concluding that, in setting standards under Section 109, EPA must separately determine the safety level for the pollutant in ques-

tion and the margin of safety it applied to that level and for each determination articulate its rationale.

CONCLUSION

For the forgoing reasons, this Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

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APPENDICES

APPENDICES

APPENDIX A

FINAL RULE OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

(Excerpts)

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[AD-FRL 3141-9(a)]

Revisions to the National Ambient Air Quality Standards for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In 1971, EPA promulgated primary and secondary national ambient air quality standards for particulate matter, measured as "total suspended particulate matter" or "TSP." The primary standards were set at 260 $\mu g/m^3$, 24-hour average not to be exceeded more than once per year, and 75 $\mu g/m^3$, annual geometric mean. The secondary standard, also measured as TSP, was set at 150 $\mu g/m^3$, 24-hour average not to be exceeded more than once per year. In accordance with sections 108 and 109 of the Clean Air Act, EPA has reviewed and revised the health and welfare criteria upon which these primary and secondary particulate matter standards were based.

On March 20, 1984 (49 FR 10408), EPA proposed changes in the standards based on its review and revision of the criteria. Today's notice announces EPA's final decisions regarding these changes. The final decisions include: (1) replacing TSP as the indicator for particulate matter for the ambient standards with a new indi-

cator that includes only those particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM_{10}), (2) replacing the 24-hour primary TSP standard with a 24-hour PM_{10} standard of 150 $\mu g/m^3$ with no more than one expected expected exceedance per year; (3) replacing the annual primary TSP standard with a PM_{10} standard of 50 $\mu g/m^3$, expected annual arithmetic mean; and (4) replacing the secondary TSP standard with 24-hour and annual PM_{10} standards that are identical in all respects to the primary standards.

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I. Background

A. Legislative Requirements Affecting This Rule

1. The Standards

Two sections of the Clean Air Act govern the establishment and revision of national ambient air quality standards (NAAQS). Section 108 (42 U.S.C. 7408) directs the Administrator to identify pollutants which may reasonably be anticipated to endanger public health or welfare and to issue air quality criteria for them. These air quality criteria are to reflect the latest scientific information useful in indicating the kind and extent of all identifiable effects on public health or welfare that may be expected from the presence of a pollutant in the ambient air.

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS for pollutants identified under section 108. Section 109(b)(1) defines a primary standard as one the attainment and maintenance of which, in the judgment of the Administrator, based on the criteria and

allowing for an adequate margin of safety, is requisite to protect the public health. A secondary standard, as defined in section 109(b)(2), must specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on the criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. Welfare effects are defined in section 302(h) (42 U.S.C. 7602(h)) to include effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility, climate, damage to and deterioration of property, hazards to transportation, and effects on economic values and on personal comfort and well-being.

The U.S. Court of Appeals for the D.C. Circuit has held that the requirement for an adequate margin of safety for primary standards was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. *Lead Industries Association v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980), *cert. denied*, 101 S. Ct. 621 (1980); *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1177 (D.C. Cir. 1981), *cert. denied*, 102 S. Ct. 1737 (1982). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, by selecting primary standards that provide an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful, but also to prevent lower pollutant levels that he finds pose an unacceptable risk of harm, even if that risk is not precisely identified as to nature or degree.

In selecting a margin of safety, EPA has considered such factors as the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, and the kind and degree of the uncertainties that must be addressed. Given that the "margin of safety" requirement by definition only comes into play where no conclusive showing of harm exists, such factors, which involve unknown or only partially quantitified risks, have their inherent limits as guides to action. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. *Lead Industries Association v. EPA*, *supra*, 647 F.2d at 1161-62.

Section 109(d) of the Act (42 U.S.C. 7409(d)) requires periodic review and, if appropriate, revision of existing criteria and standards. The process by which EPA has reviewed the original criteria and standards for particulate matter under section 109(d) is described in Sections I.C. and I.D. of this notice.

2. Related Control Requirements

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once EPA has established them. Under section 110 of the Act (42 U.S.C. 7410), States are to submit, for EPA approval, State implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. Other Federal programs provide for nationwide reductions in emissions of these and other air pollutants through the Federal Motor Vehicle Control Program under Title II of the Act (42 U.S.C. 7501 to 7534), which involves controls for automobile, truck, bus, motorcycle, and aircraft emissions, and through the development of New Source Performance Standards under section 111 (42 U.S.C. 7411) and National Emission Standards for Hazardous Air Pollutants under section 112 (42 U.S.C. 7412).

B. Particulate Matter and Original Standards for TSP

"Particulate matter" is the generic term for a broad class of chemically and physically diverse substances that exist as discrete particles (liquid droplets or solids) over a wide range of sizes. Particles originate from a variety of stationary and mobile sources. They may be emitted directly or formed in the atmosphere by transformations of gaseous emissions such as sulfur oxides, nitrogen oxides, and volatile organic substances. The chemical and physical properties of particulate matter vary greatly with time, region, meteorology and source category, thus complicating the assessment of health and welfare effects. The characteristics, origins, concentrations, and potential effects of particulate matter are discussed in more detail in the staff paper (SP) (EPA, 1982a), in the revised criteria document (CD) (EPA, 1982b), in the criteria document addendum (CDA) (EPA, 1986a) and in the staff paper addendum (SPA) (EPA, 1986b). The executive summary of the staff paper addendum is reprinted in Addendum III to this notice.

On April 30, 1971 (36 FR 8186), EPA promulgated the original primary and secondary NAAQS for particulate matter under section 109 of the Clean Air Act. The reference method for measuring attainment of these standards is the "high-volume" sampler (40 CFR Part 50, Appendix B), which collects particulate matter up to a nominal size of 25 to 45 micrometers (μm) (so-called "total suspended particulate," or "TSP"). Thus, TSP is the current indicator for the particulate matter standards. The existing primary standards for particulate matter (measured as TSP) are 260 $\mu g/m^3$, 24-hour average not to be exceeded more than once per year, and 75 $\mu g/m^3$, annual geometric mean. The secondary standard (measured as TSP) is 150 $\mu g/m^3$, 24-hour average not to be exceeded more than once per year. The scientific and technical bases for these standards are contained in the original criteria document, Air Quality Criteria for Particulate Matter (DHEW, 1969).

C. Development of Revised Air Quality Criteria for Particulate Matter

In 1976, as a result of internal Agency review and the recommendations of a committee of EPA's Science Advisory Board, EPA decided to revise the existing criteria document for particulate matter. Because of competing priorities regarding revision of other criteria documents, and because of the need to complete additional research on particulate matter, the process was scheduled to commence in 1979. With the endorsement of the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board, EPA decided to review and revise the criteria document for particulate matter concurrently with that for sulfur oxides and to produce a combined particulate matter/sulfur oxides (PM/SO_x) criteria document. On October 2, 1979 (44 FR 56731), EPA announced that it was in the process of revising the criteria document and reviewing the existing air quality standards for possible revisions.

In developing the revised criteria document, EPA has provided a number of opportunities for review and comment by organizations and individuals outside the Agency. Three drafts of the revised particulate matter/sulfur oxide criteria document, prepared by EPA's Environmental Criteria and Assessment Office (ECAO), were made available for external review on April 11, 1980 (45 FR 24913), January 29, 1981 (46 FR 9746), and October 28, 1981 (46 FR 53210). EPA received and considered numerous and often extensive comments on each of these drafts. CASAC held three public meetings to review successive drafts of the document on August 20-22, 1980 (45 FR 5164, August 4, 1980), July 7-9, 1981 (46 FA 31746, June 17, 1981), and November 16-18, 1981 (46 FR 53210, October 28, 1981). These meetings were open to the public and were attended by many individuals and representatives of organizations who provided critical reviews and new information for considera-

tion. In accordance with CASAC recommendations made after the first review meeting, five additional public meetings were held at which EPA, its consulting authors and reviewers, and other scientifically and technically qualified experts selected by EPA discussed the various chapters of the draft document and suggested ways of resolving outstanding issues (45 FR 74047, November 7, 1980; 45 FR 78224, November 25, 1980; 45 FR 76790, November 20, 1980; 45 FR 80350, December 4, 1980; 46 FR 1775, January 7, 1981).

The comments received on the successive drafts of the revised criteria document were considered in the final document, issued simultaneously with the proposal of revisions to the standards. A summary of EPA's responses to the comments on the three external review drafts of the documents is in the public docket (Docket No. A-82-37). Transcripts of the three CASAC meetings are also in the docket. In accordance with its established procedures, CASAC prepared a "closure" memorandum to the Administrator indicating its satisfaction with the final draft (December, 1981) of the criteria document and outlining key issues and recommendations. The closure memorandum, dated January 29, 1982, stated that the EPA office that prepared this document was "responsive to Committee advice as well as to comments provided by the general public . . ." The closure memorandum further stated that the criteria document "fulfills the requirements set forth in section 108 of the Clean Air Act, which requires that the criteria document 'shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare' from sulfur oxides and particulates in the ambient air." The CASAC closure memorandum on the criteria document is reprinted in its entirety in Addendum I to this notice. Following closure, minor technical and editorial refinements were made to the criteria document for printing (EPA, 1982b).

A number of scientific and technical issues were raised during the public review process. With respect to the particulate matter portions of the criteria document, the major issues included the relationship among various measures of particulate matter air quality, the implications of particle deposition and other studies for selecting a particulate matter indicator, and the development and application of criteria for deciding which epidemiological studies are most appropriate for use in revising air quality standards. A summary of these and other major scientific issues, as well as CASAC's conclusions, is included in the closure memorandum on the criteria document (Addendum I).

D. Review of the Standards: Development of Staff Paper

In the evolving process of revising the national ambient air quality standards, EPA has found it useful to prepare a document that helps bridge the gap between the scientific review of health and welfare effects contained in the criteria document and the judgments required of the Administrator in setting ambient standards. This document, known as the staff paper, has become an important element in the standards review process, providing an opportunity for public comment on proposed staff recommendations before they are presented to the Administrator.

In the spring of 1981, EPA's Office of Air Quality Planning and Standards (OAQPS) prepared the first draft of the staff paper, Review of the National Ambient Air Quality Standards for Particulate Matter: Assessment of Scientific and Technical Information. This draft staff paper, based on the then existent draft of the revised criteria document, evaluated and interpreted the available scientific and technical information most relevant to the review of the air quality standards for particulate matter and presented staff recommendations on alternative approaches to revising the standards. This

and a second draft of the paper were reviewed at two CASAC meetings on July 7-9, 1981 (46 FR 31746, June 17, 1981), and November 16-18, 1981 (46 FR 53210, October 28, 1981). Numerous written and oral comments were received on the drafts from CASAC, representatives of organizations, individual scientists, and other interested members of the public. A summary of major revisions made in response to comments on the first draft is contained in an October 31, 1981 letter to CASAC (Padgett, 1981). Following the second CASAC meeting, the staff made further revisions in response to comments and prepared an executive summary that was received by CASAC members before preparation of the closure memorandum on the staff paper. In January, 1982, EPA released the final OAQPS staff paper (EPA, 1982a), which reflects the various suggestions made by CASAC and members of the public. The January 29, 1982, CASAC closure memorandum states that the staff paper "has been modified in accordance with recommendations made by CASAC," is consistent with the criteria document, and provides the Administrator "with the kind and amount of technical guidance that will be needed to make appropriate revisions to the standard." This closure memorandum is reprinted in Addendum II to this notice.

A number of major issues were raised during the public review process. The more important issues are outlined below.

1. Substantial discussion concerned the maximum size of particles (or particle size fraction) to be used in measuring particulate matter for regulatory purposes. Some groups favored retaining TSP as an indicator; others called for alternative size-specific standards with nominal "size cuts" ("D_{50}"; see discussion in Section III.A.) of 15 μm, 10 G6mm, 5-7 G6mm, and 2.5 G6mm. After CASAC closure on the staff paper and criteria document, comments were received from one group favoring a so-called "D_0" of 10μm (approximately equivalent to a nominal size cut [D_{50}] of 6 μm).

2. Much attention was focused on selecting the level of the primary standards and on the question of which health effects studies were most appropriate for this purpose. Significant criticisms were received on the major epidemiological studies of particulate matter exposures, highlighting their limitations for use in standard setting. In a number of comments, specific suggestions for standards were made.

3. With respect to secondary standards, most attention focused on the possible need for a fine [≤2.5 G6m) particle standard designed to protect visibility.

These and other major issues are discussed more fully in the executive summary of the staff paper and in later sections of this notice. CASAC's discussion of these issues and its recommendations are contained in the closure memorandum on the staff paper (Addendum II).

E. Proposed Revisions to the Standards

On March 20, 1984 (49 FR 10408) EPA proposed a number of revisions to the primary and secondary particulate matter standards. The proposed revisions, based on the revised criteria, included:

(1) Replacing TSP as the indicator for particulate matter for the primary standards with a new indicator that includes only those particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM_{10});

(2) Changing the level of the 24-hour primary standard to a value to be selected from a range of 150 to 250 $\mu g/m^3$ and replacing the deterministic form of the standard, which permitted not more than one observed exceedance of the standard per year, with a statistical form that would permit one expected exceedance per year;

(3) Changing the level of the annual primary standard to a value to be selected from a range of 50 to 65 $\mu g/m^3$, and changing the form from an annual geometric mean to an expected annual arithmetic mean; and

(4) Replacing the current 24-hour secondary TSP standard by an annual TSP standard selected from a range of 70 to 90 $\mu g/m^3$, expected annual arithmetic mean.

The Administrator expressed an inclination to select the primary standards from the lower portions of the above ranges. With respect to the secondary standards, the Administrator was inclined to select the final standard from the upper portion of the range, but also called for comment on the alternative of using PM_{10} as the particulate matter indicator for the secondary standards and making the secondary standards identical in all respects to the primary standards. The proposal notice sets forth the rationale for these and other proposed revisions of the particulate matter NAAQS and background information related to the proposal.

F. Supplemental Criteria Revisions and Standards Review Following Proposal

Following publication of the proposal, EPA held a public meeting in Washington, D.C. on April 30, 1984 to receive comments on the proposed standards revisions. A transcript of the meeting has been placed in the public docket (Docket No. A-82-37). After the close of the original public comment period (June 5, 1985), the CASAC met on December 16-17, 1985 to review the proposal and to discuss the relevance of certain new scientific studies on the health effects of particulate matter that had emerged since the Committee completed its review of the criteria document and staff paper in January, 1982. A transcript of this meeting is also available in the Docket. Based on its preliminary review of these new studies, the Committee recommended that the Agency prepare separate addenda to the criteria document and staff paper for the purpose of evaluating the relevant new studies and discussing their potential implications for standard-setting. The Agency announced its acceptance of these

recommendations on April 1, 1986 (51 FR 11058). On July 3, 1986, EPA announced (51 FR 24392) the availability of the external review draft document entitled: Second Addendum to Air Quality Criteria for Particulate Matter and Sulfur Oxides (1982): Assessment of Newly Available Health Effects Information. At the same time, the Agency announced a supplementary comment period on the March 20, 1984 proposal to provide the public an opportunity to comment on the implications of the new studies and addenda for the final standards. On September 16, 1986, EPA announced (51 FR 32878) the availability of the draft staff paper addendum entitled Review of the National Ambient Air Quality Standards for Particulate Matter: Updated Assessment of Scientific and Technical Information. CASAC held a public meeting on October 15-16, 1986 to review both the criteria document addendum and the staff paper addendum. At this meeting, CASAC members as well as representatives of several organizations, provided critical review of both EPA documents. A transcript of the CASAC meeting has been placed in the public docket (A-82-37).

The CASAC sent a closure letter on the criteria document addendum to the Administrator dated December 15, 1986, which concludes "that this 1986 Addendum along with the 1982 Criteria Document, previously reviewed by CASAC, represent a scientifically balanced and defensible summary of the extensive scientific literature on these pollutants" (Lippman, 1986b). The closure letter on the criteria document addendum is reprinted in Addendum I of this notice. The Committee sent their closure letter on the staff paper addendum to the Administrator dated December 16, 1986, stating "The Committee believes that this document provides you with the kind and amount of technical guidance that will be needed to make appropriate revisions to the standards" (Lippman, 1986c). The closure letter on the staff paper addendum, which also discusses major issues addressed by the CASAC and the Committee's recommendations concerning these issues,

is reprinted in Addendum II to this notice. The final addenda to the criteria document (EPA, 1986a) and the staff paper (EPA, 1986b), which include revisions to reflect comments from CASAC and the public, are available from the address listed above. Where there are differences between the 1982 Criteria Document and staff paper and the more recent addenda, the addenda supersede the earlier document. The executive summary of the staff paper addendum is reprinted in Addendum III of this notice.

II. Summary of Public Comments

The following discussion summarizes in general terms the comments received from the public and from governmental agencies regarding the proposed revisions to the indicator, form, averaging times, and levels of the primary and secondary standards. Many of these comments had been made previously by the public during public deliberations on drafts of the criteria document and staff paper and were reviewed and addressed by EPA in revisions to those documents. Salient comments on all aspects of the proposal and Agency responses to those comments are summarized by category in Section VI of this notice. A more detailed description of individual comments and Agency responses has been entered in the public docket (No. A-82-37).

A. Comments on 1984 Proposal

Extensive written comments were received during the original comment period on the proposal, which closed June 5, 1985. Of some 312 written submissions, 153 were provided by individual industrial concerns or industry groups, 93 by State, local, and Federal government agencies and organizations, 32 by environmental and public interest groups, and 34 by individual private citizens.[1]

[1] This numerical distribution of comments in each category should be compared with caution. For example, the American Iron

The comments on the key elements of the proposed standards are summarized below:

(1) *Indicator for the Primary Standard:* The overwhelming majority of the comments received on this issue favored a size-selective indicator for the PM standard. Of the 147 written comments received on this issue, 108 supported the PM_{10} indicator proposed by the Agency. Most of the remaining comments were in support of alternative smaller particle size indicators including PM_6 (28 comments) and $PM_{2.5}$ (8 comments). The principal support for PM_6 came from mining and related industries.

(2) *Levels of the Primary Standards:* Comments on the proposed levels for the two primary standards were more polarized than those on the indicator. Most industry comments favored selecting the level of the standards at the upper end of the proposed ranges or above, while most of the remaining commenters favored standard levels at the lower bound of the ranges, and in some cases lower. Additional comments from individual citizens, environmental groups, and government agencies urged that the level of protection afforded by the current particulate matter standards be maintained or strengthened.

* * * *

B. Comments on Subsequent Notice

As discussed earlier in this notice, EPA announced an additional public comment period on July 3, 1986 to address the implications of new scientific studies on the health effects of particulate matter [51 FR 24392]. Approximately 20 additional written submissions were received by the close of this comment period on November

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and Steel Institute and the American Petroleum Institute submitted comments on behalf of 63 and 230 individual companies respectively, in lieu of having each of their member companies send separate comments. Similarly, comments from interest groups such as NRDC represent the views of a number of individuals.

17, 1986, 17 of which were provided on behalf of industry groups or companies, 2 from environmental groups, and 1 from a state agency. Much of the material related to evaluations of specific studies and their treatment in the staff paper addendum. The industry comments, which included submissions from consulting scientists and analysts, generally found that the new studies suffered from deficiencies that preclude placing much weight on them in standard setting. These commenters concluded that their original recommendations (summarized above) with respect to the standards remained valid. The two environmental groups felt that the findings in these new studies necessitated standards below the lower bounds of the proposed ranges.

III. Rationale for the Primary Standards

In selecting primary standards for particulate matter, the Administrator must specify: (1) the particle size fraction that is to be used as an indicator of particulate pollution; (2) the appropriate averaging times and form(s) of the standards; and (3) the numerical levels of the standards. These specifications must be considered collectively in evaluating the margin of safety afforded by particulate matter standards. Based on the assessments of relevant scientific and technical information in the criteria document and addendum, the staff paper and staff paper addendum (hereinafter "SP" and "SPA," respectively) outline a number of key factors to be considered in making decisions in each of these areas (SP, Section VI; SPA, Section IV). Both the staff and CASAC made recommendations to focus consideration on a discrete range of options. In most respects, the Administrator has adopted the recommendations and supporting reasons contained in the staff paper and addendum and the CASAC closure statements (Friedlander, 1982; Lippman, 1986c). Rather than reiterating those discussions at length, the following discussion of the standards revisions focuses primarily on those considera-

tions that were most influential in the Administrator's selection of particular options, or that differ in some respect from considerations that influenced the staff and/or CASAC recommendations.

A. Pollutant Indicator

Based on the staff assessment of the available scientific information, EPA concludes that (1) a separate particulate matter standard (as opposed to a combination standard for particulate matter and SO_2) remains a reasonable public health policy choice, and (2) given current scientific knowledge and uncertainties, a size-specific (rather than chemical-specific) indicator should be used. In assessing the information in the criteria document, the staff reached several conclusions summarized here (see SP, pp. 71-75):

(1) Health risks posed by inhaled particles are influenced both by the penetration and deposition of particles in the various regions of the respiratory tract, and by the biological responses to these deposited materials. Smaller particles penetrate furthest in the respiratory tract. The largest particles are deposited in the extrathoracic (head) region with somewhat smaller particles depositing in the tracheobronchial region. Still smaller particles can reach the deepest portion of the lung, the alveolar region.

(2) The risks of adverse health effects associated with deposition of typical ambient fine and coarse particles[2] in the thorax (tracheobronchial and alveolar regions of the respiratory tract) are markedly greater than those associated with deposition in the extrathoracic (head) region. Maximum particle penetration to the thoracic region occurs during oronasal or mouth breathing..

(3) The size-specific indicator for primary standards should represent those particles small enough to penetrate

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[2] Particles in ambient air usually occur in two somewhat overlapping size distributions, fine (diameter less than 2.5μm) and coarse (diameter larger than 2.5 pm). The two size fractions tend to have different origins and composition (SP, Appendix D).

to the thoracic region (both the tracheobronchial and alveolar regions). The risks of adverse health effects from extrathoracic deposition of typical ambient particulate matter are sufficiently low that particles depositing only in that region can safely be excluded from the indicator.

Considering these conclusions together with other information on air quality composition, respiratory tract deposition and health effects, the need to provide protection for sensitive individuals who may breathe by mouth and/or oronasally, and the similar convention on particles penetrating the thoracic region recently adopted by the International Standards Organization (ISO, 1981), the staff recommended that the size-specific indicator include particles of diameters less than or equal to a nominal 10 μm "cut point."[3] The factors considered in the original staff recommendations for a 10 μm cut point are outlined in the staff paper (SP, pp. 75-79). This indicator is referred to as "thoracic particles" (TP) in the 1982 staff paper, is now generally referred to as "PM_{10}." Such an indicator is conservative with respect to health protection in that it includes all of the particles small enough to penetrate to the sensitive alveolar region, and includes approximately the same proportion of larger particles as would be expected to reach the tracheobronchial region. It places substantially greater emphasis on controlling smaller particles than does a TSP indicator, but does not completely exclude larger particles from all control.

The assessment of more recent information on respiratory tract deposition in the criteria document and staff

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[3] The more precise term is 50% cut point or 50% diameter (D_{50}). This is the aerodynamic particle diameter for which the efficiency of particle collection is 50%. Larger particles are not excluded altogether, but are collected with substantially decreasing efficiency and smaller particles are collected with increasing (up to 100%) efficiency. Ambient samples with this cut point provide a reliable estimate of the total mass of suspended particulate matter of aerodynamic size less than or equal to 10μm. See additional discussion regarding the Federal Reference Method in section V below and in the accompanying notice revising 40 CFR Part 53.

paper addenda reinforces the conclusions reached in the original staff asesssment. In particular, the staff paper addendum found that: (1) the recent data do not provide support for an indicator that excludes all particles larger than 10 μm in diameter;[4] (2) the analysis used to support an alternative indicator with a nominal size cut of 6 G6mm (Swift and Proctor, 1982) significantly underestimated thoracic deposition of particles larger than 6 μm in diameter under natural breathing conditions; (3) the PM_{10} indicator generally includes a similar or larger fraction of the range of particles that can deposit in the tracheobronchial region, although it appears to be somewhat less conservative in this regard than previously thought with respect to large (G6$\leq$10 μm) particle deposition under conditions of natural mouthbreathing; and (4) the studies of tracheobronchial deposition generally involved adult subjects; recent information indicating even greater tracheobronchial deposition of particles in children than in adults provides an additional reason for an indicator that includes particles capable of penetration of the tracheobronchial region (SPA, p. 36). Consideration of these and the earlier conclusions led the staff to reaffirm its recommendation for a PM_{10} indicator (SPA, pp. 36-37). The CASAC also restated its recommendation for PM_{10} in its review of the proposal and the closure letter to the Administrator (Lippmann, 1986 a, c).

The Administrator accepts the recommendations of the staff and CASAC and their underlying rationale and has decided to replace TSP as the particle indicator for the primary standards with a new indicator that includes only those particules less than a nominal 10 μm in diameter, as specified in the Federal Reference Method (Appendix J to 40 CFR Part 50) being promulgated to-

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[4] The American Mining Congress (AMC, 1982) had recommended such an indicator, with a "D_0" of 10μm. EPA estimated that the "D_{50}" of this indicator would be 6 μm.

day. In defining the standards for particulate matter, this new indicator is termed PM_{10}.

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C. Level of the Standards

The original staff paper and CASAC recommendations set forth a framework for determining the levels for the proposed particulate matter standards that would protect public health with an adequate margin of safety. The discussion that follows relies heavily on that framework and on the supporting material in the staff paper and its addendum as well as the CASAC closure letters. The essential steps in this framework are summarized here.

1. Assessment of the quantitative epidemiological studies.

The criteria document and its addendum identify a small number of community epidemiological studies that are useful in determining concentrations at which particulate matter is likely to affect public health. The staff used these quantitative studies to examine concentration-response relationships and to develop numerical "ranges of interest" for possible PM_{10} standards.

A number of uncertainties associated with use of these studies must be considered in selecting an appropriate margin of safety. As discussed in the staff paper and the criteria document, and the addenda to those documents, epidemiological studies are generally limited in sensitivity and subject to inherent difficulties involving confounding variables. Moreover, many of the quantitative studies were conducted in times and places where pollutant composition may have varied considerably from current U.S. atmospheres. Most also have used British Smoke [5] or TSP as particle indicators. None of the pub-

[5] British Smoke (BS) is a pseudo-mass indicator related to small particle (aerodynamic diameter less than a nominal 4.5 μm) darkness. This particulate matter indictaor was widely used in British and other European studies. See the criteria document for a more detailed treatment of BS (CD, pp. 1-88 to 1-90 and 14-8 to 14-11).

lished studies used the proposed PM_{10} indicator. Thus, assumptions must be used to convert the various results to common (PM_{10}) units (SP, pp. 96-100; SPA pp. 9-11).

2. Identification of additional margin of safety considerations.

The criteria document identifies an additional substantial body of scientific literature that, while not providing reliable concentration-response relationships for ambient exposures, does provide important qualitative insights into the health risks associated with human exposure to particles. This literature includes both quantitative and qualitative epidemiological studies, controlled human exposure experiments, and animal toxicological studies. The staff assessed this literature to identify additional factors and uncertainties that should be considered in selecting the most appropriate margin of safety (SP, pp. 100-101; 107-111, SPA pp. 52-53; 59).

3. Selection of the levels that might be considered to provide an adequate margin of safety.

The intent of the margin of safety requirement was to direct the Administrator to set air quality standards at pollution levels below those at which adverse health effects have been found or might be expected to occur in sensitive groups. Experience with the requirement has shown that the scientific data are often so inconclusive that is is difficult to identify with confidence the lowest pollution level at which an adverse effect will occur. Moreover, in cases such as the present one, the evidence suggests that there is a continuum of effects, with the risk, incidence, or severity of harm decreasing, but not necessarily vanishing, as the level of pollution is decreased.

In the absence of clearly identified thresholds for health effects, the selection of a standard that provides an adequate margin of safety requires an exercise of informed judgment by the Administrator. The level selected will depend on the expected incidence and severity of the potential effects and on the size of the population at risk,

as well as on the degree of scientific certainty that the effects will in fact occur at any given level of pollution. For example, if a suspected but uncertain health effect is severe and the size of the population at risk is large, a more cautious approach will be appropriate than would be if the effect were less troubling or the exposed population smaller.

EPA staff originally recommended a range of potential standards for the Administrator's consideration (SP, pp. 111-114). The recommended range was below the levels at which the staff, with the concurrence of CASAC, had concluded from the available data that adverse health effects were "likely," but in the domain where the data suggested that such effects were "possible." The Administrator proposed refined ranges of standard levels that were based on the original staff and CASAC recommendations. After consideration of the new scientific evidence contained in the criteria document addendum, the staff revised its recommendations for ranges of standards (SPA, pp. 60-62). The Administrator has considered the revised assessments and the recommendations of CASAC (Lippmann, 1986b) in making his final decision on the standard levels. The rationales for the levels of the 24-hour and annual standards are presented below.

1. 24-Hour Standard

The revised staff assessment of the short-term epidemiological data is summarized in Table 1; particulate matter levels are expressed in both the original (British Smoke ["BS"] or TSP) and PM_{10} units. The "effects likely" row in Table 1 denotes concentration ranges derived from the criteria document and its addendum at or above which a consensus judgment suggests greatest certainty that the effects studied would occur, at least under the conditions that occurred in the original studies. In the "effects possible" range, the staff found credible scientific evidence suggesting the existence of adverse health effects in sensitive populations, but substantial uncertainty exists regarding the conclusions to be drawn from such evidence.

TABLE 1.—UPDATED STAFF ASSESSMENT OF SHORT-TERM EPIDEMIOLOGICAL STUDIES
(After Table 4-1, SPA)

Effects/Study	Measured British smoke levels (as $\mu g/m^3$) (24-hr.avg.)			Measured TSP levels ($\mu g/m^3$) (24/hr. avg.)	Equivalent PM_{-10} Levels ($\mu g/m^3$)
	Daily Mortality in London [1]	Aggravation of bronchitis [2]	Combined range	Small, reversible declines in lung function in children [3, 4]	Combined range [6]
Effects Likely	1000	250-*500*	250-500	.....	350-600
Effects Possible ...	?	<250*	<250	220*-420 [3]—200-250 [4]	140-350
No Significant Effects Noted				125* [4]—160 [3]	<125

* Indicates levels used for upper and lower bound of range.

[1] Various analyses of daily mortality encompassing the London winter of 1958-59, 14 winters from 1958-72, in aggregate and individually. Early winters dominated by high smoke and SO_2 from coal combustion with frequent fogs. From 1982 CD: Martin and Bradley (1960); Ware et al., (1981); Mazumdar et al. (1981). From 1986 CD Addendum: Mazumdar et al. (1982); Ostro (1984); Schwartz and Marcus (1986). Later studies show association across entire range of smoke, with no clear delineation of "likely" effects or threshold of response possible.

[2] Study of symptoms reported by bronchitis patients in London, mid-50's to early 70's; Lawther et al. (1970).

[3] Study of pollution "episodes" in Steubenville, Ohio, 1978-80; Dockery et al. (1982).

[4] Study of 1985 pollution episode in Ijmond, The Netherlands; Dassen et al. (1986).

[5] (a) *Conversion of BS readings to PM_{10} levels:* Assumes for London conditions and BS readings in the range 100-500 $\mu g/m^3$, BS $<PM_{10}<$TSP. Precise conversions are not possible. Uncertainty in measurements of BS and conversion relationships preclude quantitative estimates of range for lower BS levels. The upper bound assumption (PM_{10} = TSP = BS + 100 $\mu g/m^3$) overestimates PM_{10} levels, while the lower bound assumption (PM_{10} = BS) understates PM_{10} levels.

(b) *Conversion of TSP to PM_{10} for Dockery et al. results:* Based on analysis of particle size fraction relationships in Steubenville (Spengler et al. 1986). The lower bound TSP of 220 $\mu g/m^3$ was the peak reported for the Spring 1980 study. A PM_{15}/TSP ratio of about 0.8 occurred at a nearby site on days surrounding this peak. Using lower bound of PM_{10}/PM_{15} ratio from later year (0.8), the PM_{10} to TSP ratio estimate used in 0.64. The 160 $\mu g/m^3$ reflects peak level in Fall 1980 from episode with no significant functional decline noted.

(c) *Conversion of Dassen et al. results to PM_{10}.* Both PM indices (Respirable Suspended Particles [RSP] and TSP) reached similar levels. Results suggest TSP levels too low, but PM_{10} levels unlikely to be much higher than RSP. Thus RSP = PM_{10} assumed for conditions of higher concentrations in this study. The 125 $\mu g/m^3$ entry reflects an excursion occurring 2 days prior to date on which no decrements noted.

The data do not provide evidence of clear thresholds in exposed populations. Instead, they suggest a continuum of response for a given number of exposed individuals with both the likelihood (risk) of any effects occurring *and* the extent (incidence and severity) of any potential effect decreasing with concentration. This is particularly true for the statistical analyses of daily mortality in London. Substantial agreement exists that wintertime pollution episodes produced premature mortality in elderly and ill populations, but the range and nature of association provide no clear basis for distinguishing any particular lowest "effects likely" levels or for defining a concentration below which no association remains. The recent lung function studies in children also provide evidence of effects at concentrations in the range listed in Table 1, but the relationships are not certain enough to derive "effects likely" levels for PM_{10}. The lung function studies do, however, suggest levels below which detectable functional changes are unlikely to occur in exposed populations. Following CASAC recommendations, the staff used the combined range listed in the "effects possible" row as a starting point for developing alternative standards.

The original range proposed by the Administrator, drawn from the 1982 staff analysis, was 150 to 250 $\mu g/m^3$ PM_{10}, 24-hour average with no more than one expected exceedance per year. The lower bound of this range was derived from the original assessment of the London mortality studies. As a result of its updated assessment of reanalyses of the London mortality and more recent U.S. morbidity studies, the staff reduced the level of the lower bound of the range of interest to 140 $\mu g/m^3$ (SPA, 51), while noting that the difference between it and original lower bound (150 $\mu g/m^3$) is within the range of uncertainty associated with converting the morbidity study results from TSP to PM_{10}.

As indicated in Table 1, the study of Lawther et al. (1970) judged to provide evidence that health effects are

likely at particulate matter concentrations above 250 $\mu g/m^3$ (as BS). The effects observed in this study (related to aggravation of bronchitis) are of concern both because of their immediate impact and because of the potential for inducing longer-term deterioration of health status in a significant sensitive group. There were approximately 0.5 million bronchitics in the U.S. in 1970 (DHEW, 1973). Based on the uncertain conversion between smoke and PM_{10} outlined in Table 1, the lowest "effects likely" level derived from the Lawther study (250 $\mu g/m^3$ as BS) should be in the range of 250 to 350 $\mu g/m^3$, in PM_{10} units.

The assessment of this study formed the basis for the upper bound of the range of PM_{10} standards proposed by the Administrator in 1984. Considering this study alone, a PM_{10} standard of 250 $\mu g/m^3$ might appear to contain some margin of safety, even for the sensitive bronchitics studied, because it incorporates a conservative British Smoke/PM_{10} conversion factor and because of differences between exposure conditions in the British study and current U.S. air quality (SP, pp. 100-101). Because bronchitics are identified as a group particularly sensitive to particulate pollution, a standard of 250 $\mu g/m^3$ (as PM_{10}) also might provide some margin of safety for other, less sensitive, groups. Nevertheless, this study of bronchitics in London has inherent limitations in sensitivity that preclude derivation of unequivocal "effects of thresholds" at 250 $\mu g/m^3$ as BS, and by extension PM_{10}. The criteria document notes that associations between pollution and health status persisted at lower BS concentrations in selected, more sensitive individuals. Although the lead author of the study objects to attaching any importance to these latter findings (Lawther, 1986), EPA, with CASAC concurrence, finds no basis for asserting that this study demonstrates a population threshold at 250 $\mu g/m^3$.

In evaluating the margin of safety for a 24-hour standard, it is also important to consider the London mortality studies. A standard at the upper portion of the proposed

range (250 $\mu g/m^3$) would be well below the levels (500 to 1000 $\mu g/m^3$ as BS) of the historical London episodes in which the scientific consensus indicates that pollution was responsible for excess mortality (CD, Table 14-7). The portions of the population at greatest risk of premature mortality associated with particulate matter exposures in such episodes include the elderly and persons with pre-existing respiratory or cardiac disease. Although the extent of life shortening (days, weeks, or years) cannot be specified, the seriousness of this effect strongly justifies a margin of safety for it (below the consensus effects levels) that is larger than that warranted for the effects on bronchitics.

The staff assessment of the several reanalyses of London mortality suggests, however, that the risk of premature mortality to sensitive individuals extends to concentrations substantially lower than those which occurred in the "episodes." The more recent analyses (Mazumdar et al., 1982; Ostro, 1984; Shumway et al., 1983) provide no objective support for a population threshold below which such a risk no longer exists. Although the risk to individuals may be small at concentrations of 250 $\mu g/m^3$ and below, the number of people exposed to lower concentrations given current U.S. levels is substantially larger than the number exposed to higher levels (SPA, Table 2-1). The increased number of individuals exposed increases the risk that effects will occur in the total population exposed.

Differences in the composition of particles and gases among U.S. cities and between current conditions in the U.S. and those in London at the time the mortality and morbidity data were gathered add to the complexity of assessing the risk associated with particulate matter in the U.S. In the case of the mortality studies, however, the staff found that at least one of the more recent studies (Ozkaynak and Spengler, 1985) provides qualitative support for an association between daily mortality and par-

ticle concentrations in nearly contemporary U.S. atmospheres (SPA, pp. 43-44).

The 1982 assessment of the mortality studies and related factors prompted the Administrator to consider standard levels that extended from 250 $\mu g/m^3$ down to the lower bound of the original staff range of interest (150 $\mu g/m^3$) and even lower. The more recent analyses of the London mortality data provide additional evidence that serious adverse health effects may occur at particulate concentrations below 250 $\mu g/m^3$. These analyses have addressed a number of the uncertainties associated with the earlier studies, and have reinforced the Administrator's concern that a 24-hour standard at the upper end of the proposed range may not provide an adequate margin of safety. However, given the uncertainties in converting from BS to PM_{10} measurements, particularly at lower concentrations, and the possible differences in particulate composition between London at the time the data were gathered and the contemporary U.S., it is difficult to use these studies to set a precise level for a PM_{10} standard (SPA, pp. 49-51).

Given these difficulties, it is important to examine contemporary studies that utilize gravimetric measurements of particulate concentrations. The staff found the studies of Dockery et al. (1982) and Dassen et al. (1986) to be particularly useful. The Dockery study observed physiologically small but statistically significant decreases in lung function in a group of children exposed to peak PM_{10} levels of 140-250 $\mu g/m^3$. The decrements persisted for 2-3 weeks following the exposures. The study also suggested the possibilty of larger responses in a subset of the children, including those with existing respiratory symptoms. The Dassen study recorded similar decrements in children in the Netherlands following exposure to PM_{10} levels estimated at 200 to 250 $\mu g/m^3$, but no observable effects two days after exposure to PM_{10} levels estimated at 125 $\mu g/m^3$. The particle composition, at least in the

Dockery study, is more representative of contemporary U.S. cities and the associated aerometry provides a more reliable estimate of PM_{10} levels than do the measurements used in the London studies. It is reasonable to expect that the effects observed (small reversible reductions in lung function in children) are, in most cases, more sensitive to air pollution than those observed in the London studies. These effects are, of themselves, of uncertain significance to health, but might be associated with aggravation of respiratory symptoms in children with preexisting illness (SPA, p. 47). Long-term examination of respiratory health in the same community studied by Dockery et al. (1982) suggests that the children in that community have a higher incidence of respiratory illness and symptoms than children in communities with lower particle levels, but the data show no evidence for any persistent reduction in lung function (Ware et al., 1986). Uncertainties with respect to the effects of other pollutants (e.g., SO_2), the consistency of the changes, and exposures preclude specifying unequivocal "effects likely" levels based on this study. The staff assessment therefore suggests that short-term lung function effects in children are possible across a range of 140-250 $\mu g/m^3$ or more as PM_{10} (SPA, p. 50).

In making a decision on a final standard level, the Administrator also considered information from the more qualitative studies of PM assessed by the staff (SP, pp. 101-103; SPA, pp. 52-53). These suggest increased risks for sensitive groups (asthmatics) and risks of potential effects (morbidity in adults) not demonstrated in the more qualitative epidemiological literature. The qualitative studies do not provide clear information on effects levels, but do justify consideration of effects of particulate matter that have not been sufficiently investigated.

Based on the scientific assessment at the time, the Administrator in 1984 expressed an inclination to select a 24-hour level from the lower portion of the proposed

range of 150-250 $\mu g/m^3$. The present Administrator finds that the updated scientific assessment supports the original inclination and, if anything, suggests an even wider margin of safety is warranted. The recent analyses of daily mortality are of particular concern in this regard. The Administrator has, therefore, decided to set the final standard at the extreme lower bound of the range originally proposed; that is, at 150 $\mu g/m^3$. This standard provides a substantial margin of safety below the levels at which there is a scientific consensus that particulate matter causes premature mortality and aggravation of bronchitis. Such a margin is necessary because of the seriousness of these effects and because of the recent analyses of daily mortality that suggest adverse effects may occur at particulate matter levels well below the consensus levels. The standard is in the lower portion of the range where sensitive, reversible physiological responses of uncertain health significance are possibly, but not definitely, observed in children. Using a conservative assessment of lung function/particle relationship from Dockery et al., a change in concentration from background levels ($\sim$20 $\mu g/m^3$) to 150 $\mu g/m^3$ would produce lung function changes of at most 10 to 15% in less than 5% of exposed children (SPA, p. 48). Based on the results of Dassen et al. (1986), it appears unlikely that any functional changes would be detected one or two days following such exposures (SPA, p. 50). Thus, the maximum likely changes in lung function appear to present little risk of significant adverse responses. Standards set at a somewhat higher level would, however, present an unacceptable risk of premature mortality and allow the possibility of more significant functional changes. Furthermore, a standard level of 150 $\mu g/m^3$ is fully consistent with the recommendations of CASAC on the 24-hour standard (Lippman, 1986c).

2. Annual Standard

The updated staff assessment of important long-term epidemiological data is summarized in Table 2. Long-

term epidemiological studies are subject to additional confounding variables that reduce their sensitivity and make their interpretation more difficult than that of short-term studies. The "effects likely" levels are derived from the criteria document, but again, no clear thresholds can be identified for all effects categories. Evidence exists of effects at lower levels—the "effects possible levels"—but the evidence is inconclusive and effects are difficult to detect in the available epidemiological studies.

TABLE 2.—UPDATED STAFF ASSESSMENT OF LONG-TERM EPIDEMIOLOGICAL STUDIES (AFTER TABLE 4-2, SPA)

Effects/Study	Measured BS levels (as $\mu g/m^3$)	Measured TSP levels ($\mu g/m^3$)					Equivalent PM_{10} levels ($\mu g/m^3$)
	Increased respiratory disease, reduced lung function in children [1]	Increased respiratory disease, symptoms, small reduction in lung function in adults [2]	Increased respiratory symptoms in adults [3]	Increased respiratory symptoms and illnesses in children [4]	Reduced lung function in children [4]	Combined range	Combined range [5]
Effects likely	230-300	*180					
Effects possible	<230	*130-180	60-150 (110)	*60-114		>180	>80-90
No significant [6] effects noted		80-130			40-114	60-180 <60	40-90 <40

* Indicates levels used for upper and lower bound of range.

[1] Study conducted in 1963-65 in Sheffield, England (Lunn et al., 1967). BS levels (as $\mu g/^3$) uncertain.

[2] Studies conducted in 1961-73 in Berlin, NH (Ferris et al., 1973, 1976). Effects likely level (180 $\mu g/m^3$) based on uncertain 2-month average. Effects in lung function were relatively small.

[3] Study conducted in 1973 in two Connecticut towns. (Bouhuys et al., 1978). Exposure estimates reflect 1965-73 data in Ansonia. Median value (110 $\mu g/m^3$) used to indicate long-term concentration. No effects on lung function, but some suggestion of effects on respiratory symptoms. .

[4] Study conducted in 1976-1980 in 6 U.S. cities (Ware et al., 1986). Exposure estimates reflect 4-year averages across cities. Comparable pollution/effects gradients not noted within cities.

[5] Conversion of TSP to PM_{10} equivalents for Berlin, Ansonia studies based on estimated ratio of PM_{10}/TSP for current U.S. atmospheres (Pace, 1983). The estimated ratio ranged between 0.45 and 0.5. Conversion for six-city study based on site-specific analysis of particle size data (Spengler et al., 1986).

[6] Ranges reflect gradients in which no significant effects were detected for categories at top. Combined range reflects all columns.

Based on a recent assessment of PM_{10}/TSP ratios in areas with elevated TSP levels, the updated staff assessment revised the "effects likely" levels from the Ferris et al. (1973) study to 80 to 90 $\mu g/m^3$ as PM_{10} (SPA, p. 58). Because of limitations in sampling duration as well as the conversion to PM_{10}, this estimate is particularly uncertain. As indicated in the table, effects are possible at lower concentrations. Of greatest concern is the possibility of long-term deterioration of the respiratory system in exposed populations, the potential for which is indicated by lung function (mechanical pulmonary) changes and increased incidence of respiratory disease. One set of studies (Ferris et al., 1973, 1976) provides some evidence for a "no observed effects" level for these effects at or below 60 to 65 $\mu g/m^3$ (130 $\mu g/m^3$ as TSP) while another study (Bouhuys et al., 1978), suggests some possibility of symptomatic responses in adults at long-term median levels at or below about 50 to 55 $\mu g/m^3$ as PM_{10}. The importance of these symptomatic responses, which were unaccompanied by lung function changes, to long-term respiratory health is unclear.

The most important recent study of long-term effects is an ongoing examination of six U.S. cities (Ware et al., 1986). The study indicates the possibility of increased respiratory symptoms and illnesses in children at multi-year levels across a range of 40 to over 58 $\mu g/m^3$ as PM_{10}, but found no evidence of reduced lung function at such concentrations. This study did not find similar gradients in symptoms and illness within some of the cities, which had somewhat smaller localized pollution gradients. The results of a separate series of studies of long and intermediate term (2 to 6 weeks) exposures in a number of U.S. metropolitan areas (Ostro, 1987; Hausman et al., 1984) are more supportive of the possibility of effects within cities (respiratory related activity restrictions in adults) at comparable U.S. exposure levels. The results of these more recent studies are generally consistent with the earlier U.S. studies listed in Table 2 (SPA, 57). In

particular, the finding of symptomatic responses in children with no change in lung function (Ware et al., 1986) is consistent with similar findings in adults (Bouhuys et al., 1973) at estimated long-term PM_{10} levels down to 50 $\mu g/m^3$. However, the information available to support the existence of significant adverse effects at annual PM_{10} levels below 50 $\mu g/m^3$—especially when 24-hour levels are maintained below 150 $\mu g/m^3$—is quite limited and uncertain.

Because of the uncertainties in (SP, pp. 104-110; SPA, 54-59), as well as the limited scope and number of, these long-term quantitative studies, it is particularly important to examine the results of qualitative data from a number of epidemiological, animal, and ambient particle composition studies when evaluating what constitutes an adequate margin of safety for an annual standard. These studies justify concern for serious effects not directly evaluated in the studies listed in Table 2. Such effects include damage to lung tissues contributing to chronic respiratory disease, cancer, and premature mortality (SP, pp. 109-111). Substantial segments of the population may be susceptible to one or more of these effects (SP, p. 46). Although the qualitative data do not provide evidence for major risks of these effects at current annual particulate matter levels in most U.S. cities, the Administrator believes that the seriousness of the potential effects and the large population at risk warrant caution in setting the standard.

Based on the then current scientific assessment, the Administrator proposed in 1984 to select the annual standard level from a range of 50 to 65 $\mu g/m^3$. In the proposal, the Administrator favored a standard in the lower portion of the range. The more recent evidence, although subject to substantial uncertainty, serves to reinforce this inclination. In light of the updated assessment and in accordance with the recommendation of CASAC, the Administrator has decided to set the level of the annual standard at the lower bound of the original

range, 50 $\mu g/m^3$, expected annual arithmetic mean. This standard provides a reasonable margin of safety against the serious effect of long-term degradation in lung function, which has been judged likely at estimated PM_{10} levels above 80-90 $\mu g/m^3$ and for which there is some evidence at PM_{10} levels above 60 to 65 $\mu g/m^3$. Such a standard also provides reasonable protection against the less serious symptomatic effects for which some studies provide evidence at PM_{10} levels down to 50 $\mu g/m^3$. Although some small risk of increased respiratory symptoms may exist at this concentration, the available data are currently inconclusive on this point. Moreover, the staff and CASAC have recommended that the combined protection afforded by both 24-hour and annual standards be considered in selecting the final standard level. In this regard, analyses of air quality data show that implementation of the 24-hour standard will substantially reduce annual levels in a number of areas to below 50 $\mu g/m^3$, adding to the protection afforded by the annual standard in areas with higher 24-hour peak to mean ratios (SPA, p. 61; Freas, 1986). Based on the present evidence with respect to risks associated with annual exposures, the Administrator finds that the annual and 24-hour standards announced today provide an adequate margin of safety.

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VI. Summary of Salient Public Comments and Agency Responses

An overview of public comments on the major aspects of the March 20, 1984 proposal are presented in Section II. The most important comments on specific issues are categorized and summarized below together with Agency responses. A more comprehensive compilation of comments and Agency responses is contained in a separate Response to Comments Document that has been placed in the Docket (No. A-82-37).

A. Health Effects Criteria and Selection of the Primary Standards

1. Indicator for the Primary Standards

Comments: PM_{6} rather than PM_{10} should be used as the indicator for the primary standards because PM_{6} more accurately reflects particle deposition in the thoracic regions, provides an ample margin of safety in protecting health, and puts less emphasis on coarse particles that are relatively inert than does PM_{10}.

Agency Response: EPA considered the major analysis (Swift and Proctor, 1982) and preliminary arguments (AMC, 1982) in support of a PM_{6} indicator in developing the 1984 proposal. Although EPA deferred judgment pending additional analysis and review, the decision to propose PM_{10} and not PM_{6} was based, in part, on reservations concerning the PM_{6} indicator. The likelihood that the available data from mouthpiece studies overstated thoracic deposition during "natural" breathing was recognized in a qualitative sense by CASAC (cf. July 1981 transcript, p. 581; Docket No. A-82-37) and presented as one reason for recommending PM_{10} rather than PM_{15} or TSP as an indicator. The 1982 staff paper reflected this argument in recommending 10 μm rather than 15μm as the cutpoint for the indicator (SP, pp. 76-77). The criteria document addendum points out that assumptions used in the quantitative analyses used to support PM_{6} (Swift and Proctor, 1982) appear to underestimate thoracic particle deposition; this underestimation would reduce any margin of safety associated with an indicator derived from these data. Extension of the Swift and Proctor analysis itself suggests that approximately 10 to 20% of 10 μm partcles could penetrate to the thoracic region, rather than the 0% penetration implied by some commenters who argued for a "D_{0}" at 10 μm.

The Swift and Proctor analysis as well as several more recent analyses and experimental studies of particle depo-

sition are reviewed in the criteria document and staff paper addendum. The more recent assessments tend to support the original proposal of PM_{10}. The criteria document addendum compares the work of Miller et al. (1986), using the more recent deposition data, with the Swift and Proctor analysis and confirms that the latter understates deposition of particles larger than 6 μm in individuals who habitually breathe through the mouth.

The more recent data also show some fraction of particles of 10 μm and larger can penetrate as far as the alveolar region (CDA, Figure 2-1). The risk associated with deposition of insoluble coarse particles in this region is of particular concern because of slow clearance time (CPA, p. 2-6). Although removal in the tracheobronchial region is more rapid, deposition of coarse particles in the tracheobronchial region may be associated with bronchoconstriction and alteration of clearance mechanisms (SP, Table 5-2). The 1982 staff paper took these factors into account in the original recommendation for a 10 μm indicator that included all of the fine and a portion of the coarse fraction.

After considering these updated assessments, the EPA staff reaffirmed its original recommendation of PM_{10} as an indicator for the standards (SP, p. 32). In reviews of the March 20, 1984 proposal and of the criteria document and staff paper addenda, the CASAC also reaffirmed its recommendation for PM_{10} as an indicator (Lippman 1986 a,c). The majority of public comments on this issue also favored PM_{10}.

In summary, EPA finds that the presently available record clearly favors the PM_{10} indicator over the alternative PM_6 indicator.

Comments: Some commenters suggested that while PM_{10} represents an improvement over TSP, the fine fraction (<2.5 μm) is of relatively greater concern to health than the coarse fraction (2.5 to 10 μm). Such comment-

ers suggest that a $PM_{2.5}$ standard is needed—in addition to or, in some comments, instead of a PM_{10} standard.

Agency response: The possibility of a fine particle indicator for the primary standard was examined in the staff paper (pp. 68-70). This suggestion is based in part on the recognition that ambient particle mass and volume are distributed such that a rough division "minimum" at about 1 to 3 μm separates the "fine" (smaller) and "coarse" fractions. Each fraction has somewhat distinct chemical and physical properties and sources. The staff, however, noted a number of difficulties in using fine particles (less than a nominal 2.5 μm) alone instead of PM_{10} as the indicator for the primary standards. These include:

(1) Substantial overlap can occur between the two modes and in some cases the division minimum can disappear. Moreover, despite the differing origins and chemistries of the modes, each is chemically heterogeneous. The respiratory tract, in effect, alters the ambient distribution, with a mixture of fine and coarse modes being deposited in both the tracheobronchial and alveolar regions. Indeed, the 2.5 μm "cut" is within the size range of maximum efficiency for alveolar deposition (2 to 4 μm). The mixing of these size fractions in the respiratory tract and the heterogeneity within each fraction therefore blurs the distinction between the fractions in terms of health effects.

(2) Coarse dusts have been associated with responses such as bronchoconstriction, altered clearance and alveolar tissue damage (SP, Table 5-2). Given current information, it would be premature to ascribe all of the effects in the British, U.S., and other epidemiological studies to the fine fraction, or to any single chemical entity within that fraction.

EPA believes that a separate fine particle standard in addition to the PM_{10} standard is not warranted for the following reasons:

(1) Fine mass typically comprises on the order of 40 to 70% of PM_{10}. Therefore, the PM_{10} standards provide substantial limits on fine mass, and

(2) The limited epidemiological data presently available must provide the principal basis for any particulate matter standard. Because these data do not separate the effects of fine and coarse fractions, it is most reasonable to use these data to support a single set of standards.

(3) To the extent that emerging information suggests additional protection may be necessary, it may be more appropriate to consider the addition of chemical-specific (e.g., acid aerosols) standards rather than a fine particle standard in future primary standard revisions.

2. Interpretation of Community Epidemiological Studies

Comments: A number of commenters took issue with EPA's interpretation of the various analyses of London mortality data. These commenters suggest that (a) the London data can be used to show only an association of excess mortality with high concentrations of pollution during unique episodes in which BS and SO_2 levels exceeded 500 to 1000 $\mu g/m^3$, (b) a number of the analyses suffer from methodological flaws precluding valid conclusions, (c) the conclusion that effects may be possible at low pollution levels (e.g., <250 $\mu g/m^3$) or that there is a continuum of association with no identifiable threshold is not supportable, (d) the results of Mazumdar et al. (1982) and Ostro (1984) are more consistent with the hypothesis that particulate matter is acting as a surrogate for some other causal agent rather than as a causal agent itself, and (e) it is biologically implausible that mortality could be affected by particulate matter at levels below those shown by Lawther et al. (1970) to produce morbid effects in sensitive populations.

Agency Response: EPA's assessment of the various London mortality analysis is discussed at length in the

criteria document, the staff paper, and the addenda to these documents. The 1982 criteria document found that in the context of historical London exposures, these data indicate clear increases in daily mortality occurred with BS and SO_2 concentrations in excess of 1000 $\mu g/m^3$ with some indications of likely increases in daily mortality at levels of both pollutants in the range of 500 $\mu g/m^3$ or more (CD, Table 14-7). These original conclusions on likely effects levels, based largely on the Martin and Bradley (1960) and Ware et al. (1981) analyses, appear reasonably consistent with the original assessment of these data by the original British investigators and the 1969 criteria document. From the re-examination of these data by Ware et al. (1981) and the analysis of subsequent London winters by Mazumdar et al. (1981), the criteria document also concluded small increases in daily mortality might occur at levels below 500 $\mu g/m^3$. The more recent analyses of these data by Mazumdar et al. (1982), Ostro (1984), and Shumway et al. (1983) all serve to reinforce the possibility that effects were associated with particulate matter at concentrations below 500 $\mu g/m^3$. A number of commenters, however, including some of the original British investigators (Holland et al., 1985), object to this latter suggestion.

EPA has carefully examined these studies and the various criticisms of them submitted as comments on the proposal. In order to respond fully to these criticisms, EPA conducted more sophisticated reanalyses of the original London data to further determine the degree of reliance that can be placed on the published results (Schwartz and Marcus, 1986, CDA, Appendix A). Each of these studies does suffer from limitations and uncertainties delineated in EPA's updated asesssment (SPA pp. 17-23; 34-44); these limitations preclude definitive conclusions with respect to causality as well as identification of clear "no observed effects" levels. Nevertheless, EPA maintains its original interpretation, supported by its external science advisors, that these data at least sug-

gest the possibility of effects of particulate matter at BS levels as low as 150 $\mu g/m^3$ and possibly even lower. None of the difficulties in statistical methodology or alternative mechanisms cited by commenters provide an adequate explanation for the consistent finding of association between particulate pollution and mortality at levels below 500 $\mu g/m^3$ (as BS). The association was found for the majority of 14 winters (analyzed individually) spanning a period when pollution in London and indoor heating practices showed marked changes, and including winters in which BS levels did not exceed 250 $\mu g/m^3$. The relative consistency of the results from year-to-year despite these changes suggests that the observed effect is not explained by indoor air pollution or by long-term demographic shifts in the population. The findings were consistent among different investigators, and persisted after taking SO_2, temperature, and other weather variables into account, and after correcting for autocorrelation structure.

The principal arguments for the suggestion by some (including Mazumdar et al., 1982) that smoke may be acting as a surrogate for some more toxic pollutant or related non-pollution variable are: (1) The coefficients in the regression equations appear to increase with decreasing pollution across the 14 winters, (2) surrogate behavior is commonly observed in statistical analyses, (3) the work of Lawther suggests a threshold for morbidity at around 250 $\mu g/m^3$ as BS; hence mortality would not be expected at lower levels. While the possibility of surrogate behavior remains, the above arguments do not demonstrate that smoke acts as a surrogate for non-pollution variables. The trend toward higher coefficients with lower pollution is not clearly consistent in the Mazumdar and Ostro regressions. The existence of higher coefficients in later years, however, prompted these authors to suggest some plausible alternative to non-pollution surrogates, including: (a) The possibility that the composition of pollution changed with time, with an

increase in more toxic components, and (b) because the gravimetric mass of particles in the range under 10 μm may not have declined as much as did the black carbon content detected in the smoke measurement (Lodge, 1986), coefficients related only to smoke might be expected to increase. An additional possibility suggested by Schwartz and Marcus is that the effect of higher pollution episodes in earlier winters was blunted by public awareness (and hence reduced exposure) or by a tendency for the most susceptible individuals to succumb on an early day of a multi-day pollution episode.

The use of the Lawther morbidity data as a threshold for mortality is questionable. The London mortality data involve an unequivocal endpoint in a relatively large population (several hundred per day) over a 14 year period. As pointed out by Roth et al. (1986), although the bronchitic population studied was clearly susceptible, the effects indicator used by Lawther was a relatively insensitive one. Moreover, the threshold was determined not by rigorous analysis, but by visual examination of strip chart data. Although the principal author strongly objects (Lawther, 1982), the criteria document points out that the data do not clearly indicate an effects threshold at 250 $\mu g/m^3$. Furthermore, the simple correlation results provided by Lawther et al. (1970) suggest the possibility that a more sophisticated analysis jointly incorporating pollution and weather factors might have found increased morbidity occurring at lower levels. The recent findings of small changes in pulmonary function at lower particulate matter levels in the U.S. and the Netherlands (See Table 1) support the notion that 250 $\mu g/m^3$ (in this case as PM_{10}) is not a reliable effects threshold.

Comments: The derivation of the proposed range of levels for the annual primary standard is without scientific basis. In particular, limitations in the two major series of studies used preclude finding effects of particulate matter at the lower TSP levels shown. In addition,

the conversion of the results of these studies to PM_{10} uses an inappropriately low PM_{10}/TSP ratio.

Agency Response: EPA's assessment of studies used to derive the range of levels for the primary standard (Ferris et al., 1973, 1976; and Bouhuys et al., 1978) (CD, pp. 14-44 to 46 and SP, pages 61-62 and 104-107) was reviewed by CASAC and found to be an appropriate basis for developing revised standard levels (Friedlander, 1982). The assessment clearly points out the limitations and strengths associated with the uses of these studies.

The Ferris et al. work (See Table 2 above) involved a "longitudinal" tracking of lung function and respiratory illness in adults vs. pollution over a 12 year period in Berlin, NH, a small town in which a pulp mill was a major pollution source. As commenters note, the "effects likely" level drawn from the first year of this study is particularly uncertain, as it is based on very limited aerometry. This level, however, was not important in developing the range for the proposed standard. Because of the seriousness of the effect (a prolonged decrement in lung function), the by then decreased concentration observed in the first followup study (130 $\mu g/m^3$ as TSP), was used in developing the upper bound of the range of proposed annual standards. This concentration was based on a full year of monitoring. Based on the historical record, there can be little doubt that pollution declined in this community from 1961 to 1967, the year of the first follow-up. The nature of the particular pollution source (a pulp mill) in this study, together with a finding of very low British smoke level, indicates that a variety of particles, not just products of combustion, may be associated with adverse effects. Although commenters have suggested that other pulp mill emissions may have been responsible for the effects, ambient levels of the gaseous effluents from such sources (reduced sulfur compounds and SO_2) have not been shown to cause reduced lung function.

Estimating PM_{10} levels from this study by using typical national average PM_{10}/TSP ratios does not—as some commenters argue—clearly understate PM_{10} levels. These commenters argued that high PM_{10}/TSP ratios (e.g., 0.8) should be used because sites in the eastern US. tend to have higher ratios. The data on PM_{10}/TSP ratios, however, also show a general tendency for lower ratios to occur in industrialized areas with high TSP concentrations (Pollack, et al., 1985). Moreover, air quality measurements taken in the 1960's document the presence of substantial quantities of larger size particles, as evidenced by high dust fall levels and low soiling indexes (Kenline, 1962). The latter author concludes that this would be expected "if the majority of particles present had diameters of 10 microns or greater . . . ." EPA therefore believes that the use of ratios characteristic of industrialized areas with high particle concentrations is justified and does not contribute to any excess margin of safety in the estimated effects levels.

The Bouhuys et al. (1978) study (see Table 2 above) was used to set the lower bound for the proposed standard range, which is the level at which the final standard is being promulgated. The study found a difference in three of five respiratory symptoms but no differences in lung functions between two Connecticut towns (Ansonia and Lebanon) that had a historically large (but currently small) difference in levels of particulate matter. Although the authors believed that air pollution did not play a role in the observed differences in symptoms, the data presented do not demonstrate that the differences were due solely to other factors associated with the conduct of the study. Moreover, the finding of excess respiratory symptoms unaccompanied by a persistent change in lung function is not unique. Similar findings were also obtained in the Ferris (1973) follow up study and the more recent six city study results (Ware et al., 1986).

Some commenters argued that the estimated TSP levels derived for the Bouhuys study were too low. EPA dis-

agrees. The staff took the median TSP values reported by Bouhuys et al. over the previous several years as the relevant exposure level for this study because (1) the current gradient in pollution appeared to be too small to result in such effects, and (2) it is unreasonable to attribute all of the observed gradient in effects among urban and rural residents, as measured in 1973, to the maximum historical concentrations reported 8 to 10 years prior to that time. EPA's position is supported by the observations of Ferris et al. (1973, 1976), which show an apparent meaureable reduction in symptoms and improved lung function after only a five to six year decline in pollution. This decline suggests that any gradient in effects due to pollution eight to ten years ago would be diminished relative to effects that may be associated with the more recent past. The median value used by EPA for the Bouhuys study is, in fact, also relatively close to the weighted average of all TSP observations reported for Ansonia for the seven years preceding the Bouhuys et al., (1978) measurements, which were taken in 1973 (Lounsbury, 1986).

The approach used to convert the TSP measurements in this study to PM_{10} equivalents was also questioned. The staff rejected use of the limited (15 days) particle size data for Ansonia as unrepresentative because of questions concerning their quality and because they were taken in 1973, after particulate matter concentrations had been reduced to lower levels (SP, p. 62). Absent reliable site-specific particle size data, the staff used the median PM_{10}/TSP ratio seen at other sites in the eastern U.S. with higher than average PM_{10} levels. Because the long-term ratio can vary between 0.2 and 0.65 among such sites, such estimates are admittedly uncertain. Nevertheless, the staff examination of historical air quality and source data associated with the Bouhuys et al. study found no factors that would make the ratio unusually high or low relative to other high concentration sites in the eastern U.S. The analysis by Spengler et al. (1986)

of trends in particle size ratios from the 1970's to the present in six eastern cities suggests that the ratio of PM_{10} to TSP in early years with higher TSP levels tends to be comparable to or somewhat lower than the current ratios.

The basis for the final ambient standard is considerably strengthened by the recent results from the six-cities study (Ware et al., 1986). This work also suggests an increased risk of respiratory illness and symptoms, but no differences in lung function, in children across a gradient of pollution that extends to concentrations below those observed in the previous studies. The results are therefore qualitatively consistent with both of the earlier studies. In addition, the associated aerometry permits substantially better estimates of historical PM_{10} data. Taken together, these studies provide substantial support for an annual standard of 50 $\mu g/m^3$.

3. Margin of Safety

Comments: The Agency has incorporated an unrecognized three-fold margin of safety in the 24-hour standards through the means used to convert British Smoke measurements into PM_{10}.

Agency Response: British Smoke measurements collect particles smaller than about 4.5 microns in diameter ($PM_{4.5}$) on a substrate and then measure their absorption of light. Because the measurement depends on light absorption, it is sensitive only to the dark, "sooty" component of the particulate matter. EPA has relied on gravimetric calibrations, performed during the earlier years of the mortality and morbidity studies, that related the British Smoke measurements to particulate mass concentrations that included light-colored as well as dark particles.

The commenters note that the dark, sooty component of the particulate matter in London today constitutes

only 40% as large a fraction of the total particulate mass as it did during the period of the studies on which EPA has relied. They argue that the use of those studies to set standards for contemporary particulate pollution therefore introduces an error of a factor of 2.5 (1/0.4). Multiplying this by a typical ratio of PM_{10} to $PM_{4.5}$ of 1.2 (Lodge, 1986), the commenters arrive at an alleged error of a factor of three arising from the Agency's use of the British Smoke measurements.

The commenters rely on the unstated assumption that it is only the dark fraction of particulate pollution that affects human health, and that, since the dark fraction has declined since the time of the studies, the particulate matter in the atmosphere today is less dangerous than that present at the time of the studies. EPA disagrees with this assumption and believes that a more plausible and prudent assumption is that effects on health depend on the mass concentration of particles and not on their color.

Although it is possible that dark, carbonaceous particles were primarily responsible for the observed effects on human health in the London studies, this has not been documented, and there is no evidence to support the assumption that light-colored particles have no significant effect on human health. EPA staff has compared the composition of particulate matter in historical London and in the current U.S. and has concluded that, given the variety of particle types present in the U.S., there is no clear basis for imputing higher acute toxicity to the historical London particles (SP pp. 21-22, 100).

The commenters support their argument with the assertions that the decrease in the dark, sooty fraction of particulate matter in London has been accompanied by the elimination of pollution-related health effects, and that current excursions of fine particle mass in excess of 250 $\mu g/m^3$ have not been associated with health effects in London or elsewhere. EPA finds these assertions to be

unsupported. The studies of mortality in London over a 14-year period of declining pollution from 1958 through 1971 found that the relationship between pollution and mortality persisted throughout the period and that, in fact, the regression coefficients assigned to mortality appeared to increase over the period. (Mazumdar et al., 1982; Ostro, 1984). Moreover, continuing studies in the contemporary U.S. and Europe have suggested health effects at PM_{10} levels below 250 $\mu g/m^3$ (Dockery et al., 1982; Ozkaynak and Spengler, 1985; Dassen et al., 1986).

For these reasons, EPA concludes that it is reasonable and prudent to use the mass concentration estimates derived from historical British Smoke measurements to set ambient standards for current U.S. atmospheres under the assumption that current U.S. particles are equal in toxicity to those found in London at the time of those measurements. Any margin of safety inherent in the British Smoke/PM_{10} conversion for the earlier years when gravimetric calibrations were available is more likely to be on the order of a factor of 1.2 (the ratio of $PM_{4.5}$ to PM_{10} estimated by Lodge, 1986) rather than the factor of three suggested by the commenters. For particulate levels lower than those observed in the earlier years, EPA has supplemented the London studies with the more contemporary American and European studies using direct gravimetric measurements.

Comments: Several commenters expressed concerns that the margin of safety for the range of levels proposed for the 24-hour standard is insufficient. Commenters based these concerns on: (a) Calculations suggesting that even the lower bound may be less stringent than the current standards, (b) evidence from the more recent studies of lung function decrements in children and the analyses of London mortality data, and (c) various studies found to be mainly of qualitative value. In general, such commenters felt that, in view of the available evidence, the

standard should be set at levels at or below the lower bound of the proposed ranges.

Agency Response: The overriding consideration in selecting a standard is how well it protects public health, not its relative stringency as compared to the previous standard. EPA believes that standards chosen provide an adequate margin of safety irrespective of the relationship to the former TSP standards. Nevertheless, EPA has compared the stringency of the revised standards with that of the existing standards by estimating the number of areas that would be expected not to attain each set of standards. By this measure, the new PM_{10} standards are equivalent to or somewhat more stringent than the TSP standards (SP, Table 2-1). Commenters who calculated or asserted otherwise often did not take all of the aspects of the standards into account. The margin of safety is a function not only of level, but also of the indicator and form of the standards. The revised form, in particular, makes direct comparison of the relative stringency of proposed range with the current TSP standard inappropriate.

EPA agrees that the analyses of mortality in London justify caution in selecting a 24-hour standard level, and that the recent studies of lung function provide a useful basis for selecting the level. EPA does not, however, believe that these studies compel a standard more stringent than the one chosen. As discussed in Section III.C.1 above, uncertainties in estimating PM_{10} equivalents of low British Smoke concentrations in the later years of the London studies make it difficult to use the studies to set a precise level for a PM_{10} standard. Therefore, it is important to examine the more contemporary studies of lung function that permit a more direct estimation of PM_{10} effects levels. In considering these studies in conjunction with the London mortality and other relevant health studies, EPA finds that a 24-hour standard of 150 $\mu g/m^3$ provides an adequate margin of safety. EPA does

not agree with commenters suggestions that it is necessary to prevent any detectable changes in lung function. As discussed in Section III.C.1, a standard of 150 $\mu g/m^3$ will clearly prevent lung function decrements that might be considered to be indicative of adverse effects in well over 95% of children exposed; in fact the evidence suggests that even reversible lung function changes ($FEV_{0.75}$) in excess of 10% are unlikely at this level. EPA therefore believes that the standard provides an adequate margin of safety.

Some commenters favoring standards below the lower bounds of the proposed ranges relied on studies or analyses found by EPA and CASAC to be of little quantitative value for establishing ranges of concern. EPA considered a number of such studies in selecting a margin of safety (e.g., SPA 52-53; SP 109-111), but in EPA's judgment they do not provide a sufficient basis for establishing standards at levels below those derived from the more quantitative studies summarized in Tables 1 and 2 above.

Comments: Some commenters argued that in selecting annual standards much greater weight be given to the results of Ware et al. (1986), which suggest a possible gradient of effects at concentrations extending to the lowest levels observed in the six cities studies (25 $\mu g/m^3$).

Agency Response: EPA disagrees. EPA staff found that the pollution and effects gradient in the three cleanest cities to be too small to provide any strong suggestion of effects at such levels. Moreover, the lack of consistency for "within city" effects in this study argue against placing undue reliance on the suggestion of effects at levels outside of the range suggested by the other long-term studies of interest (Ferris et al., 1973, 1976, Bouhuys et al., 1978). In addition, the 24-hour standard provides an increased margin of safety against annual exposures at levels below 50 $\mu g/m^3$, in areas where long-term exposures are dominated by repeated short-term peaks (Freas, 1986).

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List of Subjects in 40 CFR Part 50

Air pollution control, Carbon monoxide, Ozone, Sulfur oxides, Particulate matter, Nitrogen dioxide, Lead.

Dated: June 2, 1987.

Lee M. Thomas,
Administrator.

* * * *

PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

For reasons set forth in the preamble, Part 50 of Chapter 1 of Title 40 of the Code of Federal Regulations is amended as follows:

1. The authority citation for Part 50 continues to read as follows:

Authority: Secs. 109 and 301(a), Clean Air Act, as amended (42 U.S.C. 7409, 7601(a)).

2. Section 50.6 is revised to read as follows:

§ 50.6 National primary and secondary ambient air quality standards for particulate matter.

(a) The level of the national primary and secondary 24-hour ambient air quality standards for particulate matter is 150 micrograms per cubic meter ($\mu g/m^3$), 24-hour average concentration. The standards are attained when the expected number of days per calendar year with a 24-hour average concentration above 150 $\mu g/m^3$, as determined in accordance with Appendix K to this part, is equal to or less than one.

(b) The level of the national primary and secondary annual standards for particulate matter is 50 micrograms per cubic meter ($\mu g/m^3$), annual arithmetic mean. The

standards are attained when the expected annual arithmetic mean concentration, as determined in accordance with Appendix K to this part, is less than or equal to 50 $\mu g/m^3$.

(c) For the purpose of determining attainment of the primary and secondary standards, particulate matter shall be measured in the ambient air as PM_{10} (particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers) by:

(1) A reference method based on Appendix J and designated in accordance with Part 53 of this chapter, or

(2) An equivalent method designated in accordance with Part 53 of this chapter.

APPENDIX B

STATUTORY PROVISIONS

CLEAN AIR ACT
42 U.S.C. §§ 7401, *et seq.* (1982)
(Excerpts)

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1. Section 108, 42 U.S.C. § 7408 (1982)

§ 7408. Air quality criteria and control techniques

(a) **Air pollutant list; publication and revision by Administrator; issuance of air quality criteria for air pollutants.** (1) For the purpose of establishing national primary and secondary ambient air quality standards, the Administrator shall within 30 days after the date of enactment of the Clean Air Amendments of 1970 [enacted Dec. 31, 1970] publish, and shall from time to time thereafter revise, a list which includes each air pollutant—

(A) emissions of which, in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;

(B) the presence of which in the ambient air results from numerous or diverse mobile or stationary sources; and

(C) for which air quality criteria had not been issued before the date of enactment of the Clean Air Amendments of 1970 [enacted Dec. 31, 1970], but for which he plans to issue air quality criteria under this section.

(2) The Administrator shall issue air quality criteria for an air pollutant within 12 months after he has included such pollutant in a list under paragraph (1). Air quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or

welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities. The criteria for an air pollutant, to the extent practicable, shall include information on—

(A) those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant;

(B) the types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare; and

(C) any known or anticipated adverse effects on welfare.

* * * *

2. Section 109, 42 U.S.C. § 7409 (1982)

§ 7409. National primary and secondary ambient air quality standards

(a) Promulgation

(1) The Administrator—

(A) within 30 days after December 31, 1970, shall publish proposed regulations prescribing a national primary ambient air quality standard and a national secondary ambient air quality standard for each air pollutant for which air quality criteria have been issued prior to such date; and

(B) after a reasonable time for interested persons to submit written comments thereon (but no later than 90 days after the initial publication of such proposed standards) shall by regulation promulgate such proposed national primary and secondary ambient air quality standards with such modifications as he deems appropriate.

(2) With respect to any air pollutant for which air quality criteria are issued after December 31, 1970, the Administrator shall publish, simultaneously with the issuance of such criteria and information, proposed national primary and secondary ambient air quality standards for any such pollutant. The procedure provided for in paragraph (1)(B) of this subsection shall apply to the promulgation of such standards.

(b) Protection of public health and welfare

(1) National primary ambient air quality standards, prescribed under subsection (a) of this section shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health. Such primary standards may be revised in the same manner as promulgated.

(2) Any national secondary ambient air quality standard prescribed under subsection (a) of this section shall specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air. Such secondary standards may be revised in the same manner as promulgated.

* * * *

(d) Review and revision of criteria and standards; independent scientific review committee; appointment; advisory functions

(1) Not later than December 31, 1980, and at five-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 7408 of this title and the national ambient air quality standards promulgated under this section and shall make

such revisions in such criteria and standards and promulgate such new standards as may be appropriate in accordance with section 7408 of this title and subsection (b) of this section. The Administrator may review and revise criteria or promulgate new standards earlier or more frequently than required under this paragraph.

(2) (A) The Administrator shall appoint an independent scientific review committee composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.

(B) Not later than January 1, 1980, and at five-year intervals thereafter, the committee referred to in subparagraph (A) shall complete a review of the criteria published under section 7408 ~~of this~~ title and the national primary and secondary ambient air quality standards promulgated under this section and shall recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate under section 7408 of this title and subsection (b) of this section.

(C) Such committee shall also (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.

* * * *

3. Section 112, 42 U.S.C. § 7412 (1982).

§ 7412. National emission standards for hazardous air pollutants

(a) Definitions. For purposes of this section—

(1) The term "hazardous air pollutant" means an air pollutant to which no ambient air quality standard is applicable and which in the judgment of the Administrator causes, or contributes to, air pollution which may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness.

(2) The term "new source" means a stationary source the construction or modification of which is commenced after the Administrator proposes regulations under this section establishing an emission standard which will be applicable to such source.

(3) The terms "stationary source", "modification", "owner or operator" and "existing source" shall have the same meaning as such terms have under section 111(a) [42 USCS § 7411(a)].

(b) List of hazardous air pollutants; emission standards; pollution control techniques. (1)(A) The Administrator shall, within 90 days after the date of enactment of the Clean Air Amendments of 1970 [enacted Dec. 31, 1970], publish (and shall from time to time thereafter revise) a list which includes each hazardous air pollutant for which he intends to establish an emission standard under this section.

(B) Within 180 days after the inclusion of any air pollutant in such list, the Administrator shall publish proposed regulations establishing emission standards for such pollutant together with a notice of a public hearing within thirty days. Not later than 180 days after such publication, the Administrator shall prescribe an emission standard for such pollutant, unless he finds, on the basis of information presented at such hearings, that

such pollutant clearly is not a hazardous air pollutant. The Administrator shall establish any such standard at the level which in his judgment provides an ample margin of safety to protect the public health from such hazardous air pollutant.

(C) Any emission standard established pursuant to this section shall become effective upon promulgation.

(2) The Administrator shall, from time to time, issue information on pollution control techniques for air pollutants subject to the provisions of this section.

(c) Prohibited acts; exemption. (1) After the effective date of any emission standard under this section—

(A) no person may construct any new source or modify any existing source which, in the Administrator's judgment, will emit an air pollutant to which such standard applies unless the Administrator finds that such source if properly operated will not cause emissions in violation of such standard, and

(B) no air pollutant to which such standard applies may be emitted from any stationary source in violation of such standard, except that in the case of an existing source—

(i) such standard shall not apply until 90 days after its effective date, and

(ii) the Administrator may grant a waiver permitting such source a period of up to two years after the effective date of a standard to comply with the standard, if he finds that such period is necessary for the installation of controls and that steps will be taken during the period of the waiver to assure that the health of persons will be protected from imminent endangerment.

(2) The President may exempt any stationary source from compliance with paragraph (1) for a period of not

more than two years if he finds that the technology to implement such standards is not available and the operation of such source is required for reasons of national security. An exemption under this paragraph may be extended for one or more additional periods, each period not to exceed two years. The President shall make a report to Congress with respect to each exemption (or extension thereof) made under this paragraph.

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